



2026

Evolent Clinical Guidelines for Medical Necessity Review

Interventional Cardiology

Effective January 1, 2026 – December 31, 2026

Guidelines for Clinical Review Determination

Preamble

Evolent is committed to the philosophy of supporting safe and effective treatment for patients. The medical necessity criteria that follow are guidelines for the provision of diagnostic imaging. These criteria are designed to guide both providers and reviewers to the most appropriate diagnostic tests based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice will be used when applying the guidelines. Determinations are made based on both the guideline and clinical information provided at the time of the request. It is expected that medical necessity decisions may change as new evidence-based information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient.

Guideline Development Process

These medical necessity criteria were developed by Evolent for the purpose of making clinical review determinations for requests for therapies and diagnostic procedures. The developers of the criteria sets included representatives from the disciplines of radiology, internal medicine, nursing, cardiology, and other specialty groups. Evolent's guidelines are reviewed yearly and modified when necessary following a literature search of pertinent and established clinical guidelines and accepted diagnostic imaging practices.

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Evolent Clinical Guideline 7251 for Abdominal Aortic Ultrasound

Guideline Number: Evolent_CG_7251	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for an abdominal aortic ultrasound/duplex scan.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR ABDOMINAL AORTIC ULTRASOUND

Screening for Abdominal Aortic Aneurysm

- One-time ultrasound screening ^(6,7) in men ≥ 65 years old who have ever smoked ^(8,9) **(AUC Score 8)** ⁽¹⁰⁾
- In men or women ≥ 65 years old with first-degree relatives having abdominal aortic aneurysm (AAA) ^(6,8) **(AUC Score 8)** ⁽¹⁰⁾

- One-time ultrasound screening ⁽⁶⁾ in women ≥ 65 years old who have ever smoked ⁽⁸⁾ (**AUC Score 7**) ⁽¹⁰⁾
- In men or women < 65 years old with multiple risk factors (such as having smoking history, hypertension, hyperlipidemia, inherited vascular connective tissue disorder and atherosclerotic cardiovascular disease) **OR** a first-degree relative with AAA ^(7,8)
- In patients with abdominal pain, flank pain, and lower back pain ^(6,11)
- In patients with femoral or popliteal aneurysms ⁽¹²⁾
- In patients with palpable or pulsatile abdominal mass or abdominal bruit ⁽¹¹⁾
- In patients with lower extremity peripheral artery disease (LE-PAD) presenting with intermittent claudication symptoms ⁽¹³⁾
- In patients with thromboembolic events or neurologic deficit in LE ⁽¹⁴⁾

Surveillance of Abdominal Aortic Dilation and Aneurysm

- In patients with an AAA of 2.5 cm to < 3.0 cm every 4 years and life expectancy > 2 years ⁽⁹⁾
- In patients with an AAA of 3.0 cm to < 4.0 cm every 3 years ^(6,8,9)
- In men with an AAA of 4.0 cm to < 5.0 cm **AND** in women with an AAA of 4.0 cm to < 4.5 cm every 6 months ^(8,9) (**AUC Score 8-7**) ⁽¹⁰⁾
- In men with an AAA of ≥ 5.0 cm (threshold for AAA repair is ≥ 5.5 cm diameter in men with unruptured AAA) **AND** women with an AAA of ≥ 4.5 cm every 6 months (threshold for AAA repair is ≥ 5.0 cm diameter in women with unruptured AAA) ^(8,9)
- In patients with infrarenal or juxtarenal AAAs of 4.0 to 5.4 cm every 6 months to detect expansion ⁽¹²⁾

Surveillance of Iliac Artery Aneurysm

- In patient with iliac artery aneurysm ⁽¹⁵⁾:
 - 2.0 - 2.4 cm in diameter every 3 years
 - 2.5 - 2.9 cm in diameter every 2 years
 - ≥ 3.0 cm in diameter every year

Surveillance after Abdominal Aortic Aneurysm Intervention

- In patients with AAA after open repair within 1 post-operative year and every 5 years thereafter ⁽⁹⁾
- In patients with AAA treated with EVAR (endovascular abdominal aortic aneurysm repair), baseline surveillance imaging with cardiovascular CT is typically performed within 1 month postoperatively ⁽⁹⁾, and timing of an ultrasound is defined as follows:
 - In the absence of endoleak or sac enlargement, ultrasound can be done at 12

months and then every year ^(6,8,9) (**AUC Score 7**) ⁽¹⁰⁾

- In patients with type II endoleak observed, ultrasound can be done one month after EVAR and at 6-month interval ⁽⁶⁾ during the first year and every 2-3 thereafter ⁽⁹⁾
- In patients with type II endoleak associated with an aneurysm sac, ultrasound can be done at 6-month intervals for 24 months and then annually ⁽⁶⁾ (**AUC Score 8**) ⁽¹⁰⁾
- In low-risk patients (early sac shrinkage > 10 mm and < 70 years old with no endoleak), ultrasound can be done every 2 years ⁽⁹⁾

CODING AND STANDARDS

Codes

76706, 93978, 93979

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

An abdominal ultrasound uses reflected sound waves to obtain anatomic and physiologic information of the abdominal aorta. It is commonly performed to diagnose an abdominal aortic aneurysm. An abdominal aortic aneurysm is defined as an increased internal diameter of the abdominal aorta of 3.0 cm or greater.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6

- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AAA: Abdominal aortic aneurysm

EVAR: Endovascular abdominal aortic aneurysm repair

SUMMARY OF EVIDENCE

The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm ⁽⁶⁾

Study Design: This guideline was developed by the Society for Vascular Surgery (SVS) and involved a systematic review of the literature to generate practice recommendations using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system.

Target Population: The guideline focused on patients with abdominal aortic aneurysms (AAA), including those undergoing elective and emergent repair.

Key Factors: The guideline provided recommendations for the care of patients with AAA, including the general approach to the patient, treatment options, anesthetic considerations, perioperative management, and long-term management. It emphasized the importance of surveillance imaging, the use of endovascular repair for ruptured aneurysms, and the need for antibiotic prophylaxis before dental procedures for patients with an aortic prosthesis.

2022 ACC/AHA Guideline for the Diagnosis and management of Aortic Disease ⁽⁸⁾

Study Design: This guideline was developed by the American Heart Association (AHA) and American College of Cardiology (ACC) Joint Committee on Clinical Practice Guidelines. It involved a comprehensive literature search and review of studies, reviews, and other evidence conducted on human subjects.

Target Population: The guideline focused on patients with aortic disease, including those with asymptomatic, stable symptomatic, and acute aortic syndromes.

Key Factors: The guideline provided recommendations for the diagnosis, genetic evaluation, family screening, medical therapy, endovascular and surgical treatment, and long-term surveillance of patients with aortic disease. It emphasized the role of shared decision-making, the importance of institutional interventional volume, and multidisciplinary team expertise in the care of patients with aortic disease.

ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part I: Arterial Ultrasound and Physiological Testing ⁽¹⁰⁾

Study Design: This study was a comprehensive review conducted by the American College of Cardiology Foundation (ACCF) in partnership with various specialty societies. It involved a review of common clinical scenarios where noninvasive vascular testing, including ultrasound, is frequently considered.

Target Population: The study focused on patients with peripheral vascular disease, including those with suspected or known non-coronary arterial disorders such as atherosclerotic occlusive

disease, abdominal aortic aneurysms, and other less common disorders like fibromuscular dysplasia and arterial dissection.

Key Factors: The study emphasized the importance of appropriate use criteria (AUC) for peripheral vascular ultrasound and physiological testing. It categorized clinical scenarios into appropriate, uncertain, and inappropriate use based on a scoring system. The study highlighted the need for standardized scanning protocols, interpretation by credentialed physicians, and the impact of ultrasound on clinical decision-making and therapeutic interventions.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(6,8,10)

All three articles agree on the importance of using abdominal aortic ultrasound for the diagnosis and management of aortic diseases. They emphasize the need for standardized protocols and credentialed professionals to ensure accurate and effective use of ultrasound. Additionally, they highlight the role of ultrasound in guiding clinical decision-making and therapeutic interventions.

In summary, while all three articles highlight the importance of abdominal aortic ultrasound, they differ in their focus and scope. Mohler et al 2012 emphasizes appropriate use criteria, Isselbacher et al 2022 provides a comprehensive guideline for aortic disease management, and Chaikoff et al 2018 focuses on the care of patients with AAA.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> Added third bullet to General Information Checked Medicare Advantage Line of Business Added Summary of Evidence and Analysis of Evidence
December 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1126 Abdominal Aortic Ultrasound Updated indications for Abdominal Aortic Ultrasound and organized into subsections for clarity Removed Special Note and Limitation sections Updated references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolut Clinical Guideline 7252 for Ambulatory Rhythm Monitoring

Guideline Number: Evolut_CG_7252	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations*

Purpose

To identify appropriate use for ambulatory rhythm monitoring.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR AMBULATORY RHYTHM MONITORING ⁽⁶⁾

- Palpitations are the most common indication for ambulatory heart rhythm monitoring
- Evaluation of arrhythmia drug therapy change including dosage alterations
- Patients with suspected epilepsy in whom treatment has been ineffective ⁽⁷⁾
- Patients with unexplained falls suspected to have an arrhythmic origin ⁽⁷⁾
- Suspected pacemaker malfunction, based on history and physical exam

- Syncope:
 - Symptom/rhythm correlation remains the cornerstone of the diagnostic efforts in syncope to confirm the involvement of the cardiac electrical system in the origin of syncope. The choice of monitoring modality depends on the frequency of the events
- Symptoms (**listed below**) that may be due to cardiac arrhythmias and for which ambulatory monitoring is appropriate, include:
 - Shortness of breath
 - Transient chest pain
 - Palpitations (when physical examination and/or standard ECG have not satisfactorily explained the patient's complaints)
- Transient episode of cerebral ischemia, documented cerebrovascular accident (CVA), or recent evidence of cryptogenic stroke, to evaluate for a causation rhythm disturbance (e.g., atrial fibrillation or flutter) ⁽⁸⁾
- Patient with a recent acute coronary syndrome:
 - ST-elevation myocardial infarction (STEMI) and non-STEMI when the ejection fraction is borderline (35-40%), or when frequent ventricular ectopy was noted during hospitalization
- Cardiomyopathy:
 - Hypertrophic cardiomyopathy
 - Arrhythmogenic right ventricular cardiomyopathy
 - Dilated or restrictive cardiomyopathy
- For patients found to have a significant cardiac arrhythmia or conduction disorder (**see list below**) in whom cardiac monitoring is planned for the evaluation and management of the patient:
 - Frequent Ectopy
 - Premature ventricular contraction (PVCs) ⁽⁹⁾
 - Premature atrial contraction (PACs)
 - Supraventricular tachycardia (SVT) (sustained or non-sustained) ⁽⁹⁾
 - Ventricular tachycardia (VT) (sustained or non-sustained) ⁽⁹⁾
 - Ventricular fibrillation/flutter ⁽⁹⁾
 - Unexplained or symptomatic bradycardia
 - Suspected sinus node dysfunction
 - Paroxysmal atrial fibrillation/flutter ⁽⁸⁾
 - Torsade de pointes
 - Wandering atrial pacemaker
 - Cardiac arrest ⁽⁹⁾, when electrophysiology testing or implantable cardioverter

defibrillator (ICD) implantation are not planned

- Post cardiovascular surgery:
 - Indicated for outpatient arrhythmia monitoring
- Inherited channelopathies:
 - First degree relatives of patients with idiopathic ventricular fibrillation
 - Long and short QT syndromes
 - Brugada syndrome
 - Early repolarization with high-risk features (see **background**)
 - Catecholaminergic polymorphic ventricular tachycardia
- Conduction disorders:
 - New or intermittent Left Bundle Branch Block (LBBB)
 - High-Degree Atrioventricular (AV) block
 - Second Degree AV Block
 - Transient complete Heart Block
 - Preexcitation on ECG (Wolf-Parkinson-White), symptomatic or asymptomatic
- Congenital Heart Disease (CHD):
 - Congenital aortic stenosis
 - Pediatrics patients with repaired CHD or with significant residual hemodynamic abnormalities
 - In adults with CHD at risk for tachyarrhythmia, bradyarrhythmia, heart block, or symptoms of arrhythmic origin ⁽¹⁰⁾
 - In adults with dextro-Transposition of the Great Arteries (d-TGA) with Atrial Switch (including those treated with beta blockers or other rate-lowering drug therapy) ⁽¹⁰⁾
- Autonomic Function Analysis:
 - Heart rate variability may be performed using Holter monitoring. It provides sudden cardiac death risk stratification data post-MI and in patients with heart failure. It has proved useful in patients with resynchronization devices (CRT) to evaluate optimal timing of biventricular pacing.

INDICATIONS FOR REMOVAL OF LOOP RECORDER SYSTEMS

- Implantable loop recorder (ILR) may be removed for:
 - End of battery life
 - Pain, discomfort, infection at ILR site, or patient desires the device to be removed ⁽¹¹⁾

SELECTION OF DEVICES FOR AMBULATORY RHYTHM MONITORING

Holter Monitor

Holter monitoring is used for the evaluation of a patient with symptoms suggestive of cardiac arrhythmia or conduction abnormality that occur frequently enough to be detected within a short period (24–72 h) of monitoring, preferably daily or several times a day.

Holter monitoring is useful to assess the presence and frequency of asymptomatic but potentially significant dysrhythmias, including, but not limited to atrial fibrillation, ventricular ectopy, and bradycardias.

Holter monitoring is typically used for **short term (1-2 days), and rarely longer term (up to 2 weeks)** study duration. ⁽¹²⁾

Event Recorder

Event Recorders are indicated for evaluation of frequent, but typically not daily spontaneous symptoms potentially related to tachycardia, bradycardia or conduction disorder, and likely to recur within 2–6 weeks. This form of monitoring is most useful for evaluation of symptomatic rhythm problems, as patient activation is typically needed.

Wireless Patch Monitoring Systems

Can be used as an alternative to external loop recorder or Holter Monitor for both symptomatic and asymptomatic dysrhythmias, likely to occur within 2-4 weeks.

Since it is leadless, can be accurately self-applied, and is largely water resistant, it may be more comfortable and less cumbersome than an external loop recorder, potentially improving compliance.

Unlike Holter monitors and other external monitors, it offers only 1-lead recording.

Mobile Cardiac Outpatient Telemetry

MCOT is appropriate in the evaluation of spontaneous symptoms, potentially related to tachycardia, bradycardia or conduction disorder, that are too brief, too subtle, or too infrequent to be readily documented with patient-activated monitors or Holter monitors.

MCOT is useful to assess the presence and frequency of asymptomatic but potentially significant dysrhythmias, including, but not limited to atrial fibrillation, ventricular ectopy, and bradycardias.

MCOT may be utilized when other forms of monitoring do not identify the source of symptoms (e.g., Holter Monitoring).

Implantable Loop Recorder

The implantable loop recorder (ILR) is a subcutaneous monitoring device used to monitor electrical activity of the heart over an extended period, **for up to 3 years**, to capture a spontaneous event when symptoms occur less than monthly or a few times per year.

Used for recurrent, infrequent, unexplained symptoms, potentially related to tachycardia, bradycardia or conduction disorder after a nondiagnostic initial workup (including Holter, Patch Monitor, or MCOT), with or without structural heart disease.

LIMITATIONS

- Loop recorder implantation in presence of another electrical device (AICD/PPM/CRT device etc.) is not indicated
- Loop recorder implantation post atrial fibrillation ablation is not routinely indicated and will be addressed on a case-by-case basis

CODING AND STANDARDS

Codes

33285, 33286, 93224, 93225, 93226, 93227, 93228, 93229, 93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248, 93268, 93270, 93271, 93272

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Ambulatory ECG Monitoring

Ambulatory EKG Monitoring is the continuous monitoring on an outpatient basis of the electrical activity of the heart while the patient undergoes their usual activities. The duration of the monitoring period should be long enough to capture heart rhythm abnormalities based on the patient's description of the frequency of their symptoms.

Holter Monitor

Holter monitors are continuous single and multi-lead external recorders wire-lead devices. These utilize standard wet gel electrodes worn continuously to record ECG data. Recordings may be in 2-channel (two independent bipolar leads), 3-channel, 12-channel, or EASI lead formats. They are traditionally used for 24–48 hr., although some models permit recording periods up to 30 consecutive days. They are most effective when patients maintain a diary of activities and symptoms, and mark occurrence of symptoms by pressing a button on the device. Data are analyzed post recording on a dedicated workstation.

Event Recorders

External event recorders are activated and record only at the time of detection (either automatically by the device or manually activated by the patient). They use gel electrodes connected via wires to the recording device. Event recorders are worn continuously, for varying periods of time, typically 2-weeks to one-month. They record the rhythm in a continuously renewed loop, but when activated, will store the data from the rhythm in memory. This information can be downloaded to the physician's office at the convenience of the patient post-event. Newer models can transmit triggered data automatically over a cellular network to a remote monitoring system.

Simpler non-looping post event recorders are not worn continuously. Rather, these portable devices with built-in electrodes are applied directly on the chest (or held by both hands) to record a very brief duration single-lead ECG signal during symptoms. They require that the patient be aware of the rhythm disturbance, that it lasts long enough to mobilize the device, and that the patient is able to cooperate with its use.

Patch ECG Monitors

Continuous, usually single-lead external recorders with wireless transmission (patch ECG monitors) are wearable adhesive patches with embedded electrodes that store rhythm data collected either automatically or when activated by the patient. These on-skin wearable devices eliminate the need for patient cable wires and discrete electrodes; they are comfortable to wear and water-resistant, and do not interfere with patients' daily routines. Patients can press a button to mark symptomatic episodes. Up to 7–14 days of ambulatory monitoring yields a high rate of arrhythmia identification.

MCOT

Mobile cardiac outpatient telemetry (MCOT) devices are worn continuously and have been produced with varying monitor configurations. They are capable of real-time streaming, transmitting a loop, or a single event electrogram directly to the reading center via a wireless link. Newest iterations can connect via Wi-Fi to transmit data.

The MCOT data are processed in a reading center on the back end of the monitoring system. The arrhythmic events are analyzed by trained technicians, and alarms are distributed to patient caregivers. Many MCOT devices are also equipped with real-time signal processing algorithms providing detection of cardiac arrhythmias.

ILR

The implantable loop recorder (ILR) is a patient-activated monitoring system that records ECG tracings and is indicated for patients who experience transient symptoms that may suggest a cardiac arrhythmia. The device is a programmable cardiac event recorder with looping memory and is implanted subcutaneously usually in a left pectoral or mammary location with a battery life of 15-36 months. The electrodes that sense the heart's activity are on the surface of the device, so no trans venous leads are required. This device allows continuously looping rhythm monitoring. Data are stored either when manually activated by a patient or automatically when high or low-rate parameters are met.

Early Repolarization Syndrome (ERS) High Risk Features ⁽⁹⁾

- Family history of unexplained SD < 40 years
- Family history of ERS
- High risk Early Repolarization Pattern (ERP)
 - J-waves > 2 mm
 - Dynamic changes in J point and ST morphology

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AICD: automatic implanted cardioverter defibrillator

AUC: appropriate use score

AV: atrioventricular

BBB: bundle branch block

BrS: Brugada Syndrome

CHD: congenital heart disease

CRT: cardiac resynchronization therapy

CVA: cerebrovascular accident

d-TGA: dextro-Transposition of the Great Arteries

EASI: A modified set-up that can derive 12-lead ECG signals from only 5 ECG channels

ECG: electrocardiogram

ERP: early repolarization pattern
ERS: early repolarization syndrome
ICD: implantable cardioverter defibrillator
ILR: implantable loop recorder
LBBB: left bundle branch block
MCOT: mobile cardiac outpatient telemetry
MCT: mobile cardiac telemetry
MI: myocardial infarction
mm: millimeter
PAC: premature atria complexes
PPM: permanent pacemaker
PVC: premature ventricular complexes
QT: QT interval is section on ECG
s: seconds
SCD: sudden cardiac death
SD: sudden death
ST: ST segment on ECG
STEMI: ST elevation myocardial infarction
SQTS: Short QT Syndrome
SVT: supraventricular tachycardia
VT: ventricular tachycardia
WPW: Wolfe-Parkinson-White

SUMMARY OF EVIDENCE

ESC Working Group on e-Cardiology Position Paper: accuracy and reliability of electrocardiogram monitoring in the detection of atrial fibrillation in cryptogenic stroke patients ⁽⁸⁾

Study Design: This position paper by the European Society of Cardiology Working Group on e-Cardiology discusses the accuracy and reliability of electrocardiogram (ECG) monitoring in detecting atrial fibrillation (AF) in cryptogenic stroke patients.

Target Population: Cryptogenic stroke patients, particularly those with subclinical AF.

Key Factors:

- The paper presents the definition, epidemiology, and clinical impact of cryptogenic ischemic stroke and its association with occult AF.

- It discusses classification methods for ischemic stroke and patient selection criteria for long-term ECG monitoring.
- The paper evaluates non-invasive and invasive ECG monitoring tools, highlighting the advantages of implantable cardiac monitors.
- Institutional and organizational issues such as reimbursement, patient management, data ownership, and handling are briefly touched upon.

2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry ⁽⁶⁾

Study Design: This expert consensus statement by the International Society for Holter and Noninvasive Electrocardiology (ISHNE) and the Heart Rhythm Society (HRS) reviews ambulatory ECG (AECG) and external cardiac monitoring/telemetry.

Target Population: Patients with intermittent cardiac arrhythmias, those undergoing arrhythmic drug therapy, and those needing prognosis assessment in specific clinical contexts.

Key Factors:

- The statement reviews how contemporary AECG devices acquire and process ECG signals and their clinical applications.
- It discusses the appropriate utilization of these devices in managing cardiovascular disease and promoting standards for improving AECG accuracy.
- The document provides background and framework for applying AECG techniques in clinical practice and research.
- It includes detailed sections on modalities, technology, equipment, signal acquisition, processing, and interpretation.

2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death ⁽⁹⁾

Study Design: These guidelines by the European Society of Cardiology (ESC) focus on the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death.

Target Population: Patients with ventricular arrhythmias and those at risk of sudden cardiac death.

Key Factors:

- The guidelines cover definitions, epidemiology, diagnostic tools, and therapeutic strategies for ventricular arrhythmias and sudden cardiac death.
- They provide recommendations for public basic life support, access to automated external defibrillators, and genetic testing.
- The document includes algorithms for evaluating patients with newly documented ventricular arrhythmias and managing specific structural heart diseases.

- It discusses the role of implantable cardioverter defibrillators, catheter ablation, and pharmacotherapy in long-term management.

ANALYSIS OF EVIDENCE

Shared Findings ^(6,8,9):

- **Importance of Long-term Monitoring:** All three articles emphasize the significance of long-term ECG monitoring for detecting arrhythmias, particularly atrial fibrillation and ventricular arrhythmias. Long-term monitoring increases the likelihood of detecting infrequent arrhythmias that may not be captured during short-term recordings.
- **Technological Advancements:** The articles highlight the advancements in AECG technology, including the integration of multiple biological signal sensors and the use of wireless data transmission. These advancements improve the diagnostic yield and ease of use of AECG devices.
- **Clinical Applications:** The articles discuss the clinical applications of AECG devices in managing cardiovascular disease, including the detection of arrhythmias, assessment of prognosis, and guiding therapeutic interventions.

Conclusion ^(6,8,9):

In summary, while all three articles emphasize the importance of long-term ECG monitoring and technological advancements in AECG devices, they differ in their focus on specific conditions, evaluation of monitoring tools, and recommendations for public health. Dilaveris et al 2022 focuses on atrial fibrillation detection in cryptogenic stroke patients, Steinberg et al 2017 provides a comprehensive overview of AECG technology, and Zeppenfeld et al 2022 offers detailed guidelines for managing ventricular arrhythmias and preventing sudden cardiac death.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> ● Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices ● No clinical changes ● Adjusted applicable lines of business – Medicare Advantage checked ● Added a Summary of Evidence and Analysis of Evidence

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM Cardio 1082 Cardio Policy Ambulatory EKG Monitoring • This guideline replaces UM Cardio 1085 Cardio Policy Patient Activated Event Recorder • This guideline replaces UM Cardio 1112 Cardio Policy Cardiac Telemetry • This guideline replaces UM Cardio 1146 Cardio Policy Implantation of Loop Recorder Systems

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7253 for Ankle-Brachial Index in Peripheral Artery Disease

Guideline Number: Evolent_CG_7253	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for ankle-brachial index in lower extremity peripheral artery disease.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR ANKLE-BRACHIAL INDEX IN PERIPHERAL ARTERY DISEASE

Ankle Brachial Index (ABI) With or Without Pulse Volume Recording (PVR)

- History or physical exam findings (see **Background**) suggestive of peripheral artery disease (PAD) ⁽⁶⁾ (**AUC Score 9**) ⁽⁷⁾

- Known PAD ⁽⁷⁾:
 - New or worsening signs or symptoms
 - No prior revascularization:
 - Normal baseline study **(AUC Score 7)**
 - Abnormal baseline study **(AUC Score 8)**
 - After revascularization **(AUC Score 9)**
 - Surveillance after revascularization (asymptomatic or stable signs/symptoms) ^(7,8):
 - Baseline (generally within 30 days post procedure) **(AUC Score 8)**
 - 3-, 6-, 9-, 12 months post procedure and *annually* following vein bypass graft **(AUC Score 6-8)** ⁽⁷⁾ with more frequent surveillance when:
 - Uncorrected abnormalities are detected
 - Vein conduit other than great saphenous vein was used
 - 6-, 9-, 12- months post procedure and then *every 6 months* following angioplasty/stent **(AUC Score 6-7)** ⁽⁷⁾
 - 6- and 12 months post procedure and *annually* following prosthetic bypass graft **(AUC Score 7)** ⁽⁷⁾

ABI Only

- Screening for lower extremity PAD ^(6,9) **(AUC Score 7)** ⁽⁷⁾
 - Patients at increased risk for PAD (see **Background**)

Exercise ABI ⁽⁶⁾

- Further evaluation of suspected chronic symptomatic PAD with normal or borderline resting ABI (see **Background**)
- PAD with abnormal resting ABI (see **Background**) to assess functional status and walking performance

CODING AND STANDARDS

Codes

93922, 93923, 93924

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Ankle Brachial Index (ABI) ⁽⁶⁾

The Ankle Brachial Pressure Index, known more commonly as an ABI, is calculated by dividing the resting systolic blood pressure at the ankle by the systolic blood pressures in the arm and is expressed as a ratio.

- **ABI Reference Ranges:**
 - Abnormal: ≤ 0.90
 - Borderline: 0.91-0.99
 - Normal: 1.00-1.40
 - Noncompressible: > 1.40

Pulse Volume Recording (PVR) ⁽¹⁰⁾

PVR is a non-invasive method of evaluating the arterial pressure waveform profile. A strain gauge or plethysmograph is applied in a sequential manner from thigh to ankle to assess changes in limb volume between systole and diastole. Data obtained correlates with large vessel patency and blood flow.

Patients at Increased Risk for PAD ⁽⁶⁾

- Age ≥ 65 years old
- Age 50-64 years old, with risk factors for atherosclerosis (e.g., diabetes, history of smoking, dyslipidemia, hypertension), chronic kidney disease, or family history of PAD
- Age < 50 years old, with diabetes and an additional risk factor for atherosclerosis
- Known atherosclerotic disease in another vascular bed (e.g., coronary, carotid, subclavian, renal, mesenteric artery stenosis, or abdominal aortic aneurysm)

History and Physical Examination Findings Suggestive of PAD ⁽⁶⁾

- History

- Typical claudication:
 - Pain type: aching, burning, cramping, discomfort, or fatigue
 - Location: buttock, thigh, calf, or ankle
 - Onset/offset: exertional, relief after rest (< 10 min for typical claudication)
- Atypical claudication:
 - Other nonjoint-related exertional lower extremity symptoms or symptoms of impaired walking function
 - Lower extremity muscular discomfort associated with walking that requires > 10 min rest to resolve
 - Leg weakness, numbness, or fatigue during walking without pain
- Ischemic rest pain
- History of nonhealing or slow-healing lower extremity wound ≥ 2-week duration
- Erectile dysfunction
- Physical Examination
 - Abnormal lower extremity pulse palpation (femoral, popliteal, dorsalis pedis, or posterior tibial arteries)
 - Vascular bruit (e.g., epigastric, periumbilical, groin)
 - Nonhealing lower extremity wound ≥ 2-week duration
 - Lower extremity gangrene
 - Evidence of atheroemboli in the lower extremities
 - Other physical findings suggestive of ischemia (e.g., asymmetric hair growth, nail bed changes, calf muscle atrophy, or elevation pallor/dependent rubor)

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Guideline-Directed Medical Therapy ⁽¹¹⁾

Patients with peripheral artery disease (PAD) require a comprehensive program of guideline-directed management and medical therapy (GDMT) including:

- Pharmacotherapy
 - Pharmacological treatment for PAD typically includes antiplatelet and statin

medication

- Structured exercise
- Lifestyle modifications
 - Risk factors such as diabetes mellitus and hypertension should be appropriately managed
 - Smoking cessation is also a crucial part of therapy for patients who are smokers

Acronyms/Abbreviations

ABI: Ankle-brachial index

PAD: Peripheral artery disease

PVR: Pulse volume recording

SUMMARY OF EVIDENCE

2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease ⁽⁶⁾

Study Design: This document is a clinical practice guideline developed by the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines.

Target Population: Patients with lower extremity peripheral artery disease (PAD) across multiple clinical presentation subsets (asymptomatic, chronic symptomatic, chronic limb-threatening ischemia, and acute limb ischemia).

Key Factors: The guideline provides recommendations for the management of lower extremity PAD, including the use of ABI for diagnosis. It emphasizes the importance of recognizing clinical subsets of PAD, conducting a comprehensive history and physical examination, and using diagnostic testing such as resting ABI and additional physiological testing. The guideline also addresses health disparities, risk amplifiers, and special considerations for older patients.

ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part I: Arterial Ultrasound and Physiological Testing ⁽⁷⁾

Study Design: This document is an appropriate use criteria report developed by the American College of Cardiology Foundation and other specialty societies.

Target Population: Patients undergoing peripheral vascular ultrasound and physiological testing, including those with suspected or known peripheral artery disease.

Key Factors: The report provides criteria for the appropriate use of peripheral vascular ultrasound and physiological testing, including ABI. It covers various clinical scenarios, such as evaluation for lower extremity atherosclerotic disease, surveillance of known lower extremity PAD, and screening for lower extremity atherosclerotic disease in asymptomatic individuals with

comorbidities. The criteria are based on a review of common clinical scenarios and current clinical practice guidelines.

The Society for Vascular Surgery practice guidelines on follow-up after vascular surgery arterial procedures ⁽⁸⁾

Study Design: This document is a practice guideline developed by the Society for Vascular Surgery.

Target Population: Patients undergoing follow-up after vascular surgery arterial procedures.

Key Factors: The guideline provides recommendations for follow-up after various vascular surgery procedures, including the use of ABI for surveillance. It emphasizes the importance of routine surveillance to detect significant problems early and manage them effectively. The guideline also discusses the use of duplex ultrasound and other imaging methods for follow-up and the need for individualized follow-up plans based on the patient's clinical situation

ANALYSIS OF EVIDENCE

Shared Findings ^(6–8)

- All three documents emphasize the importance of diagnostic testing, particularly the use of ABI, in the management of peripheral artery disease.
- They all highlight the need for routine surveillance and follow-up to detect and manage complications early.

Conclusion ^(6–8)

In summary, while all three documents share common themes regarding the importance of diagnostic testing and routine surveillance, they differ in their specific focus areas and the populations they address. Gornik et al 2024 provides a broader approach to PAD management, including health disparities and risk amplifiers, whereas Mohler et al 2012 and Zierler et al 2019 focus more on the appropriate use of diagnostic testing and follow-up after interventions.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none">• Added a Summary of Evidence and Analysis of Evidence

Date	Summary
May 2025	<ul style="list-style-type: none"> Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices No clinical changes Adjusted applicable lines of business – Medicare Advantage checked
December 2024	<ul style="list-style-type: none"> This guideline merges and replaces UM CARDIO_1077 Arterial PVR and Stress Arterial PVR and UM CARDIO_1078 Ankle Brachial Index Updated clinical indication and background sections Removed Limitation and Special Note sections

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evotent Clinical Guideline 7254 for Coronary Artery Bypass Graft

Guideline Number: Evotent_CG_7254	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Coronary Artery Bypass Graft.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS FOR CABG

Stable Ischemic Heart Disease ^(6,7)

One-Vessel Disease

- Proximal LAD or LCX involvement

- With ischemic symptoms on 1 antianginal drug
 - Intermediate or high-risk findings on non-invasive stress imaging (**AUC Score 7**)
- With ischemic symptoms on ≥ 2 antianginal drugs
 - Low-risk findings on non-invasive stress imaging (**AUC Score 7**)
 - Intermediate or high-risk findings on non-invasive stress imaging (**AUC Score 8**)
 - No stress test/indeterminate stress test results and $\text{FFR} \leq 0.80$ (**AUC Score 7**)

Two-Vessel Disease

- No proximal LAD involvement
 - With ischemic symptoms on ≥ 2 antianginal drugs
 - Intermediate or high-risk findings on non-invasive stress imaging (**AUC Score 7**)
 - No stress test/indeterminate stress test results and $\text{FFR} \leq 0.80$ in both vessels (**AUC Score 7**)
- Proximal LAD involvement
 - Asymptomatic
 - Intermediate or high-risk findings on non-invasive stress imaging with diabetes (**AUC Score 7**)
 - With ischemic symptoms on no antianginal drugs
 - Intermediate or high-risk findings on non-invasive stress imaging without or with diabetes (**AUC Score 7**)
 - No stress test/indeterminate stress test results and $\text{FFR} \leq 0.80$ in both vessels with diabetes (**AUC SCORE 7**)
 - With ischemic symptoms on 1 antianginal drug
 - Low-risk findings on non-invasive stress imaging with diabetes (**AUC 7**)
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC SCORE 7**) or with diabetes (**AUC SCORE 8**)
 - No stress test/indeterminate stress test results and $\text{FFR} \leq 0.80$ in both vessels without diabetes (**AUC SCORE 7**) or with diabetes (**AUC SCORE 8**)
 - With ischemic symptoms on ≥ 2 antianginal drugs
 - Low-risk findings on non-invasive stress imaging without diabetes (**AUC SCORE 7**) or with diabetes (**AUC SCORE 8**)
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC SCORE 8**) or with diabetes (**AUC SCORE 9**)
 - No stress test/indeterminate stress test results and $\text{FFR} \leq 0.80$ in both vessels without or with diabetes (**AUC SCORE 8**)

Three-vessel Disease (or more)

- Low disease complexity
 - Asymptomatic (without or with antianginal drugs)
 - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (**AUC SCORE 7**)
 - Symptomatic on no antianginal drugs
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC SCORE 7**) or with diabetes (**AUC SCORE 8**)
 - Symptomatic on 1 antianginal drug
 - Intermediate or high-risk findings on non-invasive stress imaging without or with diabetes (**AUC SCORE 8**)
 - Low-risk findings on non-invasive stress imaging with diabetes (**AUC SCORE 7**)
 - Symptomatic on ≥ 2 antianginal drugs
 - Low-risk findings on non-invasive stress imaging without diabetes (**AUC SCORE 7**) or with diabetes (**AUC SCORE 8**)
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC SCORE 8**) or with diabetes (**AUC SCORE 9**)
- Intermediate or high disease complexity
 - Asymptomatic without or with antianginal drugs
 - Low-risk findings on non-invasive stress imaging with diabetes (**AUC SCORE 7**)
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC SCORE 7**) or with diabetes (**AUC SCORE 8**)
 - Symptomatic on no antianginal drugs
 - Low-risk findings on non-invasive stress imaging without or with diabetes (**AUC SCORE 7**)
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC SCORE 7**) or with diabetes (**AUC SCORE 8**)
 - Symptomatic on 1 antianginal drug
 - Low-risk findings on non-invasive stress imaging without diabetes (**AUC SCORE 7**) or with diabetes (**AUC SCORE 8**)
 - Intermediate or high-risk findings on non-invasive stress imaging without or with diabetes (**AUC SCORE 8**)
 - Symptomatic on ≥ 2 antianginal drugs
 - Low-risk findings on non-invasive stress imaging without diabetes (**AUC SCORE 8**) or with diabetes (**AUC SCORE 9**)
 - Intermediate or high-risk findings on non-invasive stress imaging without or with diabetes (**AUC SCORE 9**)

Left Main Coronary Artery Stenosis

- Asymptomatic without or with antianginal drugs
 - Without or with additional CAD, without multivessel involvement or with low disease burden in other vessels, with ostial, midshaft, or bifurcation involvement (**AUC SCORE 8**)
 - With bifurcation involvement and intermediate or high disease burden in other vessels (**AUC SCORE 8**)
 - With ostial or midshaft stenosis and intermediate or high disease burden in other vessels (**AUC SCORE 9**)
- Symptomatic on no antianginal drugs
 - With ostial, midshaft, or bifurcation involvement, without multivessel involvement or with low disease burden in other vessels (**AUC SCORE 8**)
 - With ostial, midshaft or bifurcation involvement, with low disease burden in LMCA and/or intermediate or high disease burden in other vessels (**AUC SCORE 9**)
- Symptomatic on ≥ 1 antianginal drug (**AUC SCORE 9**)

Prior IMA To LAD Graft That Is Not Patent

- Symptomatic on ≥ 1 antianginal drug, stenoses affecting multiple territories, intermediate or high-risk findings (**AUC SCORE 7**)
- Symptomatic on ≥ 2 antianginal drugs, stenoses affecting multiple territories, intermediate or high-risk findings on non-invasive stress imaging (**AUC SCORE 8**) or stenoses affecting ≥ 3 territories and low-risk findings on non-invasive stress imaging (**AUC SCORE 7**)

NOTE: CABG can be considered as a concurrent procedure for patients with SIHD and AUC scores ≥ 7 undergoing other surgical procedures.

CODING AND STANDARDS

Codes

33508, 33510, 33511, 33512, 33513, 33514, 33516, 33517, 33518, 33519, 33521, 33522, 33523, 33530, 33533, 33534, 33535, 33536, 35600, 36140

Place/Site of Service

Inpatient hospital (21)

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Coronary Artery Disease (CAD) is narrowing or blockage of the coronary arteries (blood vessels that carry blood and oxygen to the heart). Coronary artery disease is usually caused by atherosclerosis (a buildup of fatty material and plaque inside the coronary arteries) which may cause chest pain, shortness of breath during exercise, and heart attacks.

Ischemic symptoms, aka angina pectoris, include tightness, heaviness, pressure, squeezing, or other discomfort in the chest or adjacent areas. Ischemia may also present with fatigue, faintness, or dyspnea.

Non-invasive testing includes stress testing and imaging modalities with or without contrast.

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6

- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: coronary artery bypass graft

FFR: fractional flow reserve

GDMT: guideline directed medical therapy

IMA: Internal Mammary Artery

LAD: left anterior descending coronary artery

LCA: Left coronary artery

LCX: left circumflex coronary artery

LMCA: left main coronary artery

SUMMARY OF EVIDENCE

2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization ⁽⁶⁾

Study Design: This document is a clinical practice guideline by the American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) for coronary artery revascularization. It includes recommendations based on systematic literature reviews and expert consensus.

Target Population: Patients with significant coronary artery disease undergoing coronary revascularization.

Key Factors:

Methodology: A comprehensive literature search was conducted from May 2019 to September 2019, encompassing studies, reviews, and other evidence conducted on human subjects that were published in English from PubMed, EMBASE, the Cochrane Collaboration, CINHL Complete, and other relevant databases. Additional relevant studies, published through May 2021, were also considered.

Scope: The guideline replaces the 2011 coronary artery bypass graft surgery and the 2011 and 2015 percutaneous coronary intervention guidelines, providing a patient-centric approach to guide clinicians in the treatment of patients with significant coronary artery disease undergoing coronary revascularization.

Recommendations: The document provides recommendations for various aspects of coronary artery revascularization, including improving equity of care, shared decision-making, preprocedural assessment, defining lesion severity, revascularization in STEMI and NSTEMI-ACS, and special populations and situations.

Outcomes: The guideline emphasizes the importance of improving patient outcomes through participation in clinical data registries, quality improvement programs, and collaboration with high-volume centers.

ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate use Criteria for Coronary Revascularization in Patients with Stable Ischemic Heart Disease ⁽⁷⁾

Study Design: The study involved the development of Appropriate Use Criteria (AUC) for coronary revascularization in patients with stable ischemic heart disease (SIHD). The process included drafting clinical scenarios based on patient presentations encountered in everyday practice. These scenarios were evaluated by an independent rating panel using a scoring scale from 1 to 9.

Target Population: The study focused on patients with stable ischemic heart disease (SIHD), including those with single-vessel, two-vessel, three-vessel, and left main coronary artery disease. It also considered patients with prior coronary artery bypass graft (CABG) surgery and those undergoing procedures for which coronary revascularization may be considered.

Key Factors:

Clinical Scenarios: The scenarios included information on symptom status, risk level as assessed by noninvasive testing, coronary disease burden, and in some cases, fractional flow reserve testing, presence or absence of diabetes, and SYNTAX score.

Scoring: Each indication was scored as “Appropriate” (7 to 9), “May Be Appropriate” (4 to 6), or “Rarely Appropriate” (1 to 3).

Revascularization Options: The study evaluated the appropriateness of revascularization options, including percutaneous coronary intervention (PCI) and CABG surgery, for various clinical scenarios.

Emphasis: The study emphasized the importance of guideline-directed medical therapy and antianginal therapy in the management of patients with SIHD.

Patient Preference: The study highlighted the role of shared decision-making and patient preferences in the selection of revascularization options.

ANALYSIS OF EVIDENCE

Shared Findings ^(6,7)

Both articles emphasize the importance of CABG in treating significant coronary artery disease (CAD), particularly in complex cases. They agree on several key points:

1. **CABG for Left Main Disease:**
 - Both articles recommend CABG for patients with significant left main coronary artery disease, especially when the disease is complex or involves bifurcation.
2. **CABG for Multivessel Disease:**
 - CABG is recommended for patients with three-vessel disease, particularly when the disease is complex (e.g., high SYNTAX score).
3. **CABG for Patients with Diabetes:**
 - Both articles highlight that CABG is preferred over PCI for patients with diabetes and multivessel CAD, due to better long-term outcomes.

4. CABG for Left Ventricular Dysfunction:

- CABG is recommended for patients with severe left ventricular dysfunction (ejection fraction <35%) to improve survival.

Conclusions ^(6,7)

In summary, both articles highlight the critical role of CABG in treating complex coronary artery disease, with shared conclusions on its benefits for left main disease, multivessel disease, patients with diabetes, and those with left ventricular dysfunction.

POLICY HISTORY

Date	Summary
December 2025	<ul style="list-style-type: none"> ● Added the following CPT Codes to reflect Evolent prior authorization scope: 35600, 36140
May 2025	<ul style="list-style-type: none"> ● Updated references ● Edited language for greater conformity throughout guideline ● Added Summary of Evidence and Analysis of Evidence ● Added third general information bullet
November 2024	<ul style="list-style-type: none"> ● This Guideline replaces UM Cardio 1096 Aorta Coronary Bypass Surgery ● Corrected typo under “Three-Vessel Disease” heading ● Edited “Three-Vessel Disease” to “Three-Vessel Disease (or more)”

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care



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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7255 for Aortic Valve Replacement

Guideline Number: Evolent_CG_7255	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Aortic Valve Replacement. Aortic valve replacement is a cardiac surgery in which a patient's failing aortic valve is replaced with an alternate healthy valve.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS FOR SURGICAL AORTIC VALVE REPLACEMENT (SAVR)

Asymptomatic

- Severe aortic stenosis (AS) and left ventricular ejection fraction (LVEF) < 50%, and ≤ 80 years of age as an alternative to TAVR after shared decision-making related to valve durability and expected longevity, including the following situations ^(6,7):

- AVA (aortic valve area) $\leq 1.0 \text{ cm}^2$ (or AVA index $\leq 0.6 \text{ cm}^2/\text{m}^2$) on resting echo, **LVEF < 20%**, high or intermediate risk for surgery:
 - Aortic valve peak velocity $\geq 4 \text{ m/s}$ or mean gradient $\geq 40 \text{ mmHg}$ on resting echo **(AUC Score 7)**
- AVA (aortic valve area) $\leq 1.0 \text{ cm}^2$ (or AVA index $\leq 0.6 \text{ cm}^2/\text{m}^2$) on resting echo, **LVEF < 20%**, low flow/low gradient with flow reserve on dobutamine echocardiogram (i.e., truly severe AS):
 - High or intermediate surgical risk **(AUC Score 7)**
- AVA (aortic valve area) $\leq 1.0 \text{ cm}^2$ (or AVA index $\leq 0.6 \text{ cm}^2/\text{m}^2$) on resting echo, **LVEF 20%-49%**, low flow/low gradient with flow reserve on dobutamine echocardiogram (i.e., truly severe AS):
 - High or intermediate surgical risk **(AUC Score 8)**
 - Low surgical risk **(AUC Score 9)**
- AVA (aortic valve area) $\leq 1.0 \text{ cm}^2$ (or AVA index $\leq 0.6 \text{ cm}^2/\text{m}^2$) on resting echo, LVEF **20%-49%**, low flow/low gradient with no flow reserve on dobutamine echocardiogram but with very calcified valve on imaging (Transthoracic echocardiogram (TTE) or Computed tomography (CT)) or projected valve area calculation suggesting truly severe AS:
 - High or intermediate surgical risk **(AUC Score 7)**
- Very severe AS (defined as an aortic velocity $\geq 5 \text{ m/s}$), LVEF $\geq 50\%$, as an alternative to TAVR ^(6,7):
 - High or intermediate surgical risk **(AUC Score 7)**
 - Low surgical risk **(AUC Score 8)**
- Severe AS with low surgical risk and exercise test demonstrating decreased exercise tolerance or a fall in systolic blood pressure of $\geq 10 \text{ mmHg}$ from baseline to peak exercise ⁽⁶⁾
- Severe AS and LVEF $\geq 50\%$ with low surgical risk (see **Definitions**), with a high-risk profession (e.g., airline pilot), lifestyle (competitive athlete), or anticipated prolonged period away from medical supervision **(AUC Score 7)** ⁽⁷⁾
- Severe AS, LVEF $\geq 50\%$, with ≥ 1 predictor(s) of symptom onset or of rapid progression such as: rapid progression (peak velocity increasing $> 0.3 \text{ m/s}$ per year, severe valve calcification, elevated B-type natriuretic peptide (BNP > 3 times normal ⁽⁶⁾), significant left ventricular hypertrophy (LVH) in the absence of hypertension), and a negative exercise stress test (ETT), as an alternative to TAVR ⁽⁷⁾:
 - High or intermediate surgical risk **(AUC Score 7)**
 - Low surgical risk **(AUC Score 8)**
- Chronic severe aortic regurgitation (AR) and LV systolic dysfunction (LVEF $< 50\%$) ⁽⁶⁾
- Severe AR with normal LV systolic function (LVEF $> 55\%$) but with severe LV dilation (left ventricular end-systolic dimension (LVESD) $> 50 \text{ mm}$) ⁽⁶⁾

- Moderate AS/AR with jet velocity of ≥ 4 m/s with LVEF $< 50\%$ ⁽⁶⁾
- Severe AS undergoing another cardiac surgery/ascending aortic surgery (**AUC Score 9**) ^(6,7)
- Severe AR undergoing another cardiac surgery ⁽⁶⁾

Symptomatic ^(8,9)

- SAVR is recommended with severe high-gradient AS who have symptoms by history or on exercise testing
- SAVR is reasonable in symptomatic patients with:
 - Low-flow/low-gradient severe AS with reduced LVEF **AND**
 - With a low dose Dobutamine stress study that shows an aortic velocity > 4.0 m/s (or mean pressure gradient > 40 mmHg) **AND**
 - With a valve area > 1.0 cm² at any Dobutamine dose
- SAVR is indicated for symptomatic patients with severe AR regardless of LV systolic function

CODING AND STANDARDS

Codes

33405, 33406, 33410, 33411, 33412, 33413, 33530, 35500

Places of Service

Inpatient hospital (21)

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- Aortic Stenosis Severity ⁽⁶⁾:
 - Severe AS: Aortic peak velocity (Vmax) ≥ 4 m/s or mean gradient ≥ 40 mm Hg
 - Aortic valve area (AVA) typically is ≤ 1.0 cm² (or valve index (AVAi) 0.6 cm²/m²) but is not required to define severe AS
 - Very severe AS: aortic Vmax ≥ 5 m/s or mean gradient ≥ 60 mm Hg
 - Low flow/low gradient severe AS: defined by a mismatch between reduced aortic valve area (AVA, < 1 cm²) and a non-severe increase mean valve pressure gradient (i.e., < 40 mmHg) with an impaired left ventricular stroke volume (volume of blood pumped with each beat, similar to LVEF) at rest. This creates a diagnostic and therapeutic dilemma: choosing between aortic valve replacement (AVR) and medical therapy vs optimal medical therapy alone. Low dose dobutamine stress echo (DSE) is recommended a means of increasing stroke volume with a simultaneous reassessment of aortic valve indices. **Flow reserve** is defined as a 20% increase in stroke volume demonstrated by DSE. DSE can yield three possible results in this situation:
 - Truly severe AS: Significant increase in stroke volume (i.e. flow reserve is demonstrated) and mean valve gradient (>40 mmHg). Aortic valve is severely stenotic, and the low gradient measured at rest is a consequence of the LV contractile dysfunction.
 - Pseudo-severe AS: Significant increase in stroke volume and persistent low mean valve gradient (< 40 mmHg) and AS does not meet the hemodynamic criteria to be defined as severe.
 - Undetermined AS severity: Absence of significant increase in stroke volume and mean valve gradient (< 40 mmHg): In this case, DSE fails to demonstrate an increase in stroke volume (lack of flow reserve) and the AS severity grade remains undetermined. In this situation clinicians have to rely on the morphologic features of the valve on imaging (such as cardiac CT). ⁽¹⁰⁾
- Risk Assessment for Valve Procedures:
 - **STS-PROM** (Society of Thoracic Surgeons predicted risk of surgical mortality) ^(6,7)
 - Low risk: STS score $< 3\%$
 - Intermediate: STS score 3 to 8%
 - High: STS score $> 8\%$ to $<15\%$
 - Extreme: STS score $\geq 15\%$
 - Society of Thoracic Surgeons (STS) Risk Calculations
 - The Society of Thoracic Surgeons Risk Calculator is an interactive algorithm that produces risk percentages for a range of likelihoods based on specific patient characteristics. It draws from a database that incorporates data on all adult

cardiac surgical procedures. The calculator can be located at the Society of Thoracic Surgeons website, www.sts.org.

- Anatomical Factors Favoring TAVR over Surgical Valve Replacement

Note: These anatomical factors increase surgical risk and are not captured in the STS-PROM risk calculator ⁽⁷⁾

- Porcelain aorta: severe calcification of the ascending aorta extending to the aortic arch preventing safe cannulation or cross-clamping during cardiac surgery ⁽¹¹⁾
- Hostile chest: condition(s) that make chest surgery prohibitively risky such as radiation damage, abnormal chest wall anatomy (i.e. severe kyphoscoliosis), complications from prior surgery ⁽¹²⁾

- Abnormal ETT Definition ⁽⁷⁾

- In relation to the functional assessment of seemingly asymptomatic AS, an abnormal exercise stress test is characterized by:
 - Exercise-induced angina
 - Excessive dyspnea early in exercise
 - Dizziness, or syncope
 - Limited exercise capacity (below age and sex-specific predicted metabolic equivalent of task, or MET)
 - Abnormal blood pressure response (e.g., hypotension during exercise or failure to increase blood pressure with exercise)
 - Increase in the mean gradient with exercise ≥ 18 mmHg (i.e., on stress echocardiogram)

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AR: Aortic regurgitation

AS: Aortic stenosis

AUC: Appropriate use criteria

AVA: Aortic valve area

cm: centimeter

CT: Computed tomography

ETT: Exercise Treadmill Test

LVEF: Left ventricular ejection fraction

LVEDD: Left ventricular end-systolic dimension

m: meter

mm: millimeter

SAVR: Surgical aortic valve replacement

STS-PROM: Society of Thoracic Surgeons predicted risk of mortality score

TAVR: Transcatheter Aortic Valve Replacement

TTE: Transthoracic echocardiogram

SUMMARY OF EVIDENCE

ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for the Treatment of Patients With Severe Aortic Stenosis ⁽⁷⁾

Study Design: This study developed Appropriate Use Criteria (AUC) for the treatment of patients with severe aortic stenosis (AS). It involved a multidisciplinary writing group and an independent rating panel that scored various clinical scenarios based on guidelines, clinical trial data, and expert opinion.

Target Population: Patients with severe AS, including those with asymptomatic, symptomatic, high-gradient, low-flow, and low-gradient AS. The study also considered patients with associated conditions such as coronary artery disease (CAD) and other valve pathologies.

Key Factors: The study identified 95 clinical scenarios and up to six potential treatment options for each. The rating panel scored each indication from 1 to 9, categorizing them as "Rarely Appropriate," "May Be Appropriate," or "Appropriate." The criteria considered factors such as symptom status, left ventricular (LV) function, surgical risk, and the presence of concomitant coronary or other valve disease.

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease ⁽⁶⁾

Study Design: This guideline report by the American College of Cardiology (ACC) and American Heart Association (AHA) provides recommendations for the management of patients with valvular heart disease, including aortic stenosis.

Target Population: Adult patients with valvular heart disease, specifically those with aortic stenosis. The guidelines cover both symptomatic and asymptomatic patients, as well as those with low-flow, low-gradient AS.

Key Factors: The guidelines emphasize the importance of accurate diagnosis, timing of intervention, and risk assessment. They recommend intervention for symptomatic patients with severe AS and for asymptomatic patients with severe AS and impaired LV function. The guidelines also discuss the use of exercise testing, biomarkers, and imaging techniques such as

echocardiography and cardiac computed tomography (CT) to assess the severity of AS and guide treatment decisions.

2021 ESC/EACTS Guidelines for the management of valvular heart disease ⁽⁹⁾

- **Study Design:** This guideline report by the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) provides recommendations for the management of valvular heart disease, including aortic stenosis.
- **Target Population:** Patients with aortic stenosis, including those with symptomatic and asymptomatic severe AS. The guidelines also address patients with associated conditions such as CAD and other valve pathologies.
- **Key Factors:** The guidelines recommend intervention for symptomatic patients with severe AS and for asymptomatic patients with severe AS and impaired LV function. They emphasize the importance of a multidisciplinary Heart Team approach and the use of imaging techniques such as echocardiography, CT, and cardiac magnetic resonance (CMR) to assess the severity of AS and guide treatment decisions. The guidelines also discuss the role of biomarkers and exercise testing in risk stratification

ANALYSIS OF EVIDENCE

Shared Findings ^(6,7,9)

Indications for SAVR:

- All three articles agree that SAVR is indicated for patients with severe symptomatic aortic stenosis (AS). This includes patients with exertional dyspnea, heart failure, angina, syncope, or presyncope.
- SAVR is also recommended for asymptomatic patients with severe AS and left ventricular ejection fraction (LVEF) <50%.

Evaluation and Diagnosis:

- The importance of thorough evaluation using echocardiography to assess the severity of AS, valve morphology, and left ventricular function is emphasized in all three articles.
- Additional diagnostic tools such as computed tomography (CT) and cardiac magnetic resonance (CMR) are recommended for further assessment in cases where echocardiographic data are inconclusive.

Risk Stratification:

- All articles highlight the need for careful risk stratification using tools like the Society of Thoracic Surgeons (STS) score and the European System for Cardiac Operative Risk Evaluation (EuroSCORE) to determine the suitability of patients for SAVR.
- Factors such as frailty, comorbidities, and anatomical considerations are important in the decision-making process

Conclusion ^(6,7,9)

SAVR remains a crucial intervention for patients with severe symptomatic AS, with strong evidence supporting its benefits in improving survival, symptoms, and left ventricular function. The shared conclusions across the three articles highlight the importance of thorough evaluation, risk stratification, and timely intervention. However, the differing conclusions on the timing of intervention, choice of intervention, and role of medical therapy reflect the evolving nature of clinical practice and the need for individualized patient care.

In summary, while SAVR is consistently recommended for severe symptomatic AS, the decision to intervene in asymptomatic patients and the choice between SAVR and TAVR should be guided by a comprehensive assessment of patient-specific factors and the expertise of the Heart Team. The integration of advanced diagnostic tools and biomarkers further enhances the ability to tailor treatment to individual patient needs.

POLICY HISTORY

Date	Summary
December 2025	<ul style="list-style-type: none"> Fixed “stoke” typo in Background to “stroke” Added the following CPT Codes to reflect Evolent prior authorization scope: 33413, 35500
June 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices Removed Special Note and Potential Exclusion sections Updated Asymptomatic indication for SAVR per recent societal guidelines Updated background
November 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1095 Aortic Valve Replacement

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evotent Clinical Guideline 7256 for Aorto-Renal Endarterectomy or Bypass Surgery

Guideline Number: Evotent_CG_7256	<u>Applicable Codes</u>	
<i>"Evotent" refers to Evotent Health LLC and Evotent Specialty Services, Inc.</i> <i>© 2016 - 2026 Evotent. All rights Reserved.</i>		
Original Date: May 2016	Last Revised Date: July 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Medical Necessity

In order to review a request for medical necessity, the following items must be submitted for review:

- Cardiologist/Nephrologist/Vascular Surgeon note that prompted request
- Renal Artery Duplex/Retroperitoneal Duplex/Magnetic Resonance Angiography (MRA) Renal/Computed Tomography Angiography (CTA) Renal/Renal Angiogram reports

Purpose

Indications for determining medical necessity for Aorto-Renal Endarterectomy or Bypass Surgery. Renal artery stenosis (RAS) is the narrowing of one or both renal arteries. Surgery may be recommended for people with RAS caused by fibromuscular dysplasia or RAS that does not improve with medication. In an endarterectomy, the plaque is cleaned out of the artery, leaving the inside lining smooth and clear. To create a bypass, a vein or synthetic tube is used to connect the kidney to the aorta.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a

robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR AORTO-RENAL ENDARTERECTOMY OR BYPASS SURGERY

NOTE: For patients who are not a candidate for percutaneous intervention (PI)

- Patients with fibro-muscular dysplastic RAS with ^(6,7):
 - Complex disease that extends into the segmental arteries **AND**
 - Macro-aneurysms
- Patients with atherosclerotic RAS ^(6,7)
 - With multiple small renal arteries **OR** early primary branching of the main renal artery
- Patients with atherosclerotic RAS in combination with pararenal aortic reconstructions (in treatment of aortic aneurysms or severe aortoiliac occlusive disease) ^(6,8)

Potential Exclusions

- Advanced disease - Creatinine level > 3-4 mg/dL; kidney length < 8 cm
- Limited life expectancy
- Bleeding diathesis; recent myocardial infarction (MI)
- Pregnancy

CODING AND STANDARDS

Codes

35560

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid

☒	Medicare Advantage
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BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AAA: abdominal aortic aneurysm

AUC: appropriate use criteria

DTAA: descending thoracic aortic aneurysm

MI: myocardial infarction

PAU: penetrating atherosclerotic ulcer

PI: percutaneous intervention

RAS: renal artery stenosis

SUMMARY OF EVIDENCE

2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS) ⁽⁶⁾

The 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases provide the following information on aorto-renal revascularization:

- Renal artery revascularization is only recommended in specific situations, such as in patients with renal artery disease due to fibromuscular dysplasia or in those with flash pulmonary edema or congestive heart failure. For atherosclerotic renal artery disease, routine revascularization is not recommended, as several randomized trials have shown no benefit over medical therapy alone.
- The guidelines state that open surgical revascularization should be considered for patients with complex anatomy of the renal arteries, after a failed endovascular procedure, or during open aortic surgery. However, the guidelines do not provide specific study details or design for aorto-renal endarterectomy or bypass surgery.

Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations) ⁽⁷⁾

Study Design: This document is a compilation of the 2005 and 2011 ACCF/AHA guideline recommendations for the management of patients with peripheral artery disease (PAD). It includes recommendations developed by the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines in collaboration with several other societies.

Target Population: The guidelines are intended for patients with peripheral artery disease, including those with lower extremity PAD, renal artery disease, mesenteric artery disease, and aneurysms of the abdominal aorta and its branch vessels.

Key Factors: The document provides detailed recommendations on various aspects of PAD management, including vascular history and physical examination, diagnostic methods, treatment options (such as lipid-lowering drugs, antihypertensive drugs, diabetes therapies, smoking cessation, antiplatelet and antithrombotic drugs), exercise and rehabilitation, endovascular and surgical treatments, and follow-up care.

2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease ⁽⁸⁾

Study Design: This guideline was developed by the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. It involved a systematic review of literature, including randomized controlled trials, registries, nonrandomized comparative and descriptive studies, case series, cohort studies, systematic reviews, and expert opinion.

Target Population: The guideline focuses on patients with lower extremity peripheral artery disease (PAD), including those with claudication, critical limb ischemia, acute limb ischemia, and other related conditions.

Key Factors: Recommendations: The guideline provides evidence-based recommendations for the diagnosis and management of PAD, including medical therapy, structured exercise, revascularization, and wound healing therapies. Resting ABI, exercise treadmill ABI, TBI, TcPO₂, and SPP are recommended for diagnosing PAD and assessing perfusion. Antiplatelet agents, statins, antihypertensive agents, smoking cessation, glycemic control, and other therapies are recommended to reduce cardiovascular events and improve limb outcomes. Supervised exercise programs are recommended to improve functional status and quality of life. Endovascular and surgical revascularization are recommended for patients with lifestyle-limiting claudication and critical limb ischemia. Comprehensive care by an interdisciplinary team is recommended to achieve complete wound healing and preserve a functional foot.

ANALYSIS OF EVIDENCE

Analysis ^(6–8):

The evidence from these articles collectively supports the use of both aorto-renal endarterectomy and bypass surgery in managing aorto-renal disease. The choice between the

two depends on various factors, including the extent of the disease, patient comorbidities, and surgical expertise. Endarterectomy is favored for localized stenosis due to its simplicity and lower complication rates, while bypass surgery is preferred for extensive disease due to its durability and effectiveness in complex cases. Long-term outcomes are generally favorable for both techniques, with patient selection and individualized treatment plans being crucial for optimal results.

Shared Conclusions:

- Importance of Revascularization: All three articles emphasize the significance of revascularization in managing peripheral arterial diseases (PAD), including aorto-renal conditions. They agree that revascularization can improve symptoms, prevent disease progression, and reduce the risk of cardiovascular events.
- Patient Selection: The articles concur that patient selection is crucial for determining the appropriate intervention. Factors such as the severity of symptoms, anatomical considerations, and comorbidities must be evaluated to decide between endarterectomy and bypass surgery.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none"> ● Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> ● No substantive clinical content changes ● Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices ● Updated references
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM 1268 Aorto-Renal Endarterectomy or Bypass Surgery
March 2024	<ul style="list-style-type: none"> ● Updated references ● Updated AUC scores ● Added Clinical Reasoning for AUC scores

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guideline 7257 for Arterial Duplex in Peripheral Artery Disease

Guideline Number: Evolent_CG_7257	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for arterial duplex of the extremities. Duplex ultrasound imaging of the major arteries in the extremities is for assessing any abnormalities in the blood flow.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR ARTERIAL DUPLEX OF EXTREMITIES

Lower Extremity Peripheral Artery Disease (PAD) ^(6–9)

- Suspected acute limb ischemia (i.e., pale, pulseless, cold, painful limb) **(AUC Score 9)** ⁽⁸⁾
- History or physical exam findings (see **Background**) suggestive of peripheral artery

disease (PAD) **(AUC Score 9)** ⁽⁷⁾

- Known PAD ⁽⁸⁾:
 - New or worsening signs or symptoms
 - No prior revascularization:
 - Normal baseline study **(AUC Score 7)**
 - Abnormal baseline study **(AUC Score 8)**
 - After revascularization **(AUC Score 9)**
- Functionally limiting claudication with inadequate response to guideline-directed medical therapy (GDMT) when revascularization is being considered ⁽⁷⁾
- Annual surveillance of known PAD on GDMT (stable signs/symptoms) ⁽⁷⁾
- Chronic limb threatening ischemia (CLTI) to assist in revascularization strategy ⁽⁷⁾
 - Includes evaluation of great saphenous vein for use as bypass conduit
- Suspected PAD with inconclusive resting ankle brachial index (ABI) and physiological testing (including exercise ABI) ⁽⁷⁾
- Palpable popliteal mass to exclude popliteal aneurysm ⁽⁶⁾
- Femoral or popliteal aneurysms to exclude contralateral femoral or popliteal aneurysms ⁽⁶⁾
- Suspected femoral artery pseudoaneurysm following a catheter-related procedure ⁽⁸⁾:
 - Initial evaluation:
 - Pulsatile groin mass **(AUC Score 9)**
 - Bruit or thrill over groin **(AUC Score 8)**
 - Significant hematoma **(AUC Score 7)**
 - Severe pain within groin post procedure **(AUC Score 7)**
 - Follow-up examination 1 month after the original injury for asymptomatic femoral artery pseudoaneurysm
- Surveillance after revascularization (asymptomatic or stable signs/symptoms) ^(8,9):
 - Baseline (generally within 30 days post procedure) **(AUC Score 8)**
 - 3-, 6-, 9-, 12 months post procedure and *annually* following vein bypass graft **(AUC Score 6-8)** with more frequent surveillance when:
 - Uncorrected abnormalities are detected
 - Vein conduit other than great saphenous vein was used
 - 6-, 9-, 12- months post procedure and then *every 6 months* following angioplasty/stent **(AUC Score 6-7)**
 - 6- and 12 months post procedure then *annually* following prosthetic bypass graft **(AUC Score 7)**

- Aneurysm surveillance ⁽⁶⁾:
 - Annual follow-up asymptomatic femoral artery true aneurysm
 - Annual follow-up asymptomatic popliteal artery aneurysm

Upper Extremity PAD ⁽⁸⁾

- Arm or hand claudication (**AUC Score 8**)
- Finger discoloration or ulcer (**AUC Score 8**)
- Unilateral cold painful hand (**AUC Score 8**)
- Raynaud's phenomenon (**AUC Score 5**)
- Suspected positional arterial obstruction (e.g., thoracic outlet syndrome) (**AUC Score 7**)
- Upper extremity trauma with suspicion of vascular injury (**AUC Score 8**)
- Discrepancy in arm pulses or blood pressure discrepancy of > 20 mm Hg between arms (**AUC Score 6**)
- Peri-clavicular bruit (**AUC Score 5**)
- Pre-op radial artery harvest (e.g., for CABG) (**AUC Score 7**)
- Presence of pulsatile mass or hand ischemia after upper extremity vascular access (**AUC Score 8**)
- Presence of bruit after upper extremity access for intervention (**AUC Score 8**)
- Post revascularization:
 - Baseline within 30 days (**AUC Score 8**)
 - New or worsening symptoms
 - Following stent or bypass (**AUC Score 8**)
 - Post trauma (**AUC Score 8**)
 - Surveillance (asymptomatic or stable signs/symptoms)
 - After 6 months, then annually following vein bypass graft (**AUC Score 7**)
 - After 6 months (**AUC Score 6**), then annually (**AUC Score 7**) after prosthetic bypass graft

CODING AND STANDARDS

Codes

93925, 93926, 93930, 93931

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

History and Physical Examination Findings Suggestive of PAD ⁽⁷⁾

- **History**
 - Typical claudication:
 - Pain type: aching, burning, cramping, discomfort, or fatigue
 - Location: buttock, thigh, calf, or ankle
 - Onset/offset: exertional, relief after rest (< 10 min for typical claudication)
 - Atypical claudication:
 - Other nonjoint-related exertional lower extremity symptoms or symptoms of impaired walking function
 - Lower extremity muscular discomfort associated with walking that requires > 10 min rest to resolve
 - Leg weakness, numbness, or fatigue during walking without pain
 - Ischemic rest pain
 - History of nonhealing or slow-healing lower extremity wound ≥ 2-week duration
 - Erectile dysfunction
- **Physical Examination**
 - Abnormal lower extremity pulse palpation (femoral, popliteal, dorsalis pedis, or posterior tibial arteries)
 - Vascular bruit (e.g., epigastric, periumbilical, groin)
 - Nonhealing lower extremity wound ≥ 2-week duration
 - Lower extremity gangrene

- Evidence of atheroemboli in the lower extremities
- Other physical findings suggestive of ischemia (e.g., asymmetric hair growth, nail bed changes, calf muscle atrophy, or elevation pallor/dependent rubor)

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Guideline-Directed Medical Therapy ⁽¹⁰⁾

Patients with peripheral artery disease (PAD) require a comprehensive program of guideline-directed management and medical therapy (GDMT) including:

- Pharmacotherapy
 - Pharmacological treatment for PAD typically includes antiplatelet and statin medication
- Structured exercise
- Lifestyle modifications
 - Risk factors such as diabetes mellitus and hypertension should be appropriately managed
 - Smoking cessation is also a crucial part of therapy for patients who are smokers

Acronyms/Abbreviations

ABI: Ankle brachial index

CABG: Coronary Artery Bypass Grafting

CLTI: Chronic limb-threatening ischemia

GDMT: Guideline-directed medical therapy

PAD: Peripheral artery disease

SUMMARY OF EVIDENCE

Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations) ⁽⁶⁾

Study Design: This document is a compilation of the 2005 and 2011 ACCF/AHA guideline recommendations for the management of patients with peripheral artery disease (PAD). It

includes recommendations developed by the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines in collaboration with several other societies.

Target Population: The guidelines are intended for patients with peripheral artery disease, including those with lower extremity PAD, renal artery disease, mesenteric artery disease, and aneurysms of the abdominal aorta and its branch vessels.

Key Factors: The document provides detailed recommendations on various aspects of PAD management, including vascular history and physical examination, diagnostic methods, treatment options (such as lipid-lowering drugs, antihypertensive drugs, diabetes therapies, smoking cessation, antiplatelet and antithrombotic drugs), exercise and rehabilitation, endovascular and surgical treatments, and follow-up care.

2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease ⁽⁷⁾

Study Design: This document is the 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease. It was developed by the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines in collaboration with several other organizations.

Target Population: The guidelines are intended for clinicians treating patients with lower extremity peripheral artery disease across its multiple clinical presentation subsets, including asymptomatic PAD, chronic symptomatic PAD, chronic limb-threatening ischemia, and acute limb ischemia.

Key Factors: The document provides comprehensive recommendations on the clinical assessment, diagnostic testing, medical therapy, preventive foot care, exercise therapy, revascularization techniques, management of chronic limb-threatening ischemia, and acute limb ischemia. It also addresses special considerations such as risk amplifiers, health disparities, and management of PAD in older patients.

ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part I: Arterial Ultrasound and Physiological Testing ⁽⁸⁾

Study Design: This document is the 2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing, Part I: Arterial Ultrasound and Physiological Testing. It was developed by the American College of Cardiology Foundation Appropriate Use Criteria Task Force in partnership with several other societies.

Target Population: The criteria are intended for patients undergoing peripheral vascular ultrasound and physiological testing for various arterial disorders, including cerebrovascular disease, renal artery stenosis, mesenteric artery stenosis, abdominal aortic disease, and lower and upper extremity arterial disease.

Key Factors: The document provides detailed criteria for the appropriate use of peripheral vascular ultrasound and physiological testing based on various clinical scenarios. It includes indications for testing, surveillance after revascularization, and follow-up care. The criteria are

intended to guide clinicians in maximizing the appropriate use of noninvasive vascular laboratory testing for the care of patients with peripheral vascular disorders

ANALYSIS OF EVIDENCE

Shared Findings ^(6–8)

- All three documents emphasize the importance of comprehensive clinical assessment and diagnostic testing for the management of PAD and other arterial disorders.
- They all highlight the significance of medical therapy, including the use of lipid-lowering drugs, antihypertensive drugs, and antiplatelet therapy, in reducing the risk of cardiovascular events in patients with PAD.
- The documents stress the importance of exercise therapy and preventive foot care in improving patient outcomes and preventing complications.
- They all recognize the need for revascularization techniques, including endovascular and surgical treatments, in managing severe cases of PAD and other arterial disorders.

Conclusion ^(6–8)

In summary, while all three documents share common goals in improving the management of PAD and other arterial disorders, they differ in their specific focus areas and the scope of their recommendations. Anderson et al. 2013 provides a broad overview of PAD management, Gornik et al. 2024 focuses on lower extremity PAD, and Mohler et al. 2012 emphasizes the appropriate use of diagnostic testing.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> • Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> • Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices • No clinical changes • Removed code description • Adjusted applicable lines of business – Medicare Advantage checked

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1076 Arterial Duplex • Updated clinical indication and background sections • Removed Limitation and Special Note sections

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7258 for Device Interrogation and Programming

Guideline Number: Evolent_CG_7258	<u>Applicable Codes</u>	
<i>"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc.</i> <i>© 2026 Evolent. All rights Reserved.</i>		
Original Date: January 2026	Last Revised Date: July 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

The purpose of device interrogation is to monitor the device's performance and adjust the settings as needed.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR DEVICE INTERROGATION

In-Person Device Interrogation and Programming ⁽⁶⁾

- Recommended at 2-12 weeks after implantation
- May be performed routinely every 6-12 months for pacemakers and every 3 months for implantable ICDs to ensure the integrity of the device components and to improve longevity

- Should be performed for any Cardiovascular Implantable Electronic Devices (CIEDs) when alerts are triggered by remote monitoring

Transtelephonic Monitoring ⁽⁶⁾

- Used only in patients with Cardiovascular Implantable Electronic Monitoring (CIEMs) that do not have remote monitoring or remote interrogation capabilities

Remote Monitoring ⁽⁶⁾

- Recommended for all patients with CIEMs equipped with this capability
- Should be utilized for all patients whose CIEMs or leads are under recall or advisory status
- Frequency should be programmed to minimize pacemaker battery drain (typically every three months), unless circumstances (such as lead or pulse generator advisory or patient rhythm disturbances) demand closer surveillance

Remote Pacemaker Interrogation ^(7,8)

- Routine remote interrogation may be performed every 3 months from last interrogation
- Cardiac Resynchronization Therapy with Pacemaker (CRT-P) interrogation may be performed every 3 months, either in-person or remotely
- When device interrogation reveals that the battery is approaching elective replacement indicator (90 days or less), interrogation may be performed monthly

NOTE: Interrogation includes device programming, if performed on the same day

AICD Interrogation ^(7,8)

- Routine/surveillance Automatic Implantable Cardiac Defibrillator (AICD)/ Cardiac Resynchronization Therapy with ICD (CRT-D)/ subcutaneous Implantable Cardioverter Defibrillator (ICD) interrogation may be performed every 3 months, either in-person or remotely
- When device interrogation reveals that the battery is approaching elective replacement indicator (90 days or less), interrogation may be performed monthly

NOTE: Interrogation includes device programming, if performed on the same day

Wearable ICD Interrogation ⁽⁹⁾

- Life Vest™ or wearable defibrillator interrogation may be performed every 30 days

Loop Recorder Interrogation ⁽⁶⁾

- Routine loop recorder interrogation in person or remotely may be done monthly

Urgent Interrogation ⁽⁷⁾

- Appropriate when recent shock therapy from an ICD or any symptom or finding since previous CIED (ICD, pacemaker, or loop recorder) evaluation for which an interrogation earlier than recommended guideline frequency could help yield a diagnosis, or if permanent adjustment(s) were made during the last evaluation
- Indicated when recent interrogation shows battery voltage in elective replacement indicator range or end of life indicator range (may differ by device type and manufacturer)

NOTE: Interrogation includes device programming, if performed on the same day

Physiologic Interrogation ⁽⁶⁾

- Available when the patient has an implanted device which monitors transthoracic impedance as an index of fluid volume status, or the patient has an implanted device that monitors pulmonary artery pressure
- Monitoring may be performed in-person or remotely every 30 days when there is documentation that the data will be used to adjust diuretic or other heart failure therapies
- Monitoring may be performed urgently when the patient reports new or worsening symptoms of heart failure when the information obtained will be used to adjust medical therapy

Exclusions

- Remote and in-person interrogation cannot be reported at the same time

INDICATIONS FOR DEVICE PROGRAMMING

Routine Device Programming

- Device Programming is indicated within 72 hours of device implantation or pulse generator change and may be indicated during a routine follow-up visit 2-12 weeks after device implantation. ^(6,10)
- Device Programming may also be indicated during routine follow-up visits that occur every 3-12 months for pacemakers, and every 3-6 months for ICDs and resynchronization devices. ⁽⁶⁾

Patient-related Indications

- Changes in the clinical status or cardiovascular symptom frequency/severity that may affect device function. ⁽⁷⁾
- Changes in disease therapy or medication regimen if the change may influence the underlying cardiac rhythm or device functioning ⁽¹¹⁾

- A lower rate cutoff is recommended for patients taking antiarrhythmic medications (e.g., Amiodarone, Multaq, Propafanone) that may reduce the heart rate at which clinical tachycardia is achieved

Disease-specific Programming ⁽⁶⁾

- In patients with heart failure, AICD or CRT-D device programming through AV optimization to prevent recurrent heart failure decompensation is recommended
- Unnecessary shocks due to rapid responses to supraventricular tachydysrhythmias (e.g., atrial fibrillation and flutter) and T-wave oversensing in channelopathies may occur. Device reprogramming may be indicated to reduce these occurrences.

Device-related Indications

- Device evaluation during Interrogation demonstrates lead malfunctioning, lead recall(s), or that the battery is approaching its end of life ⁽⁶⁾
- When the device delivers frequent or inappropriate shocks, device programming is indicated to optimize the programming therapy zones by modifying the device's operational parameters. Examples of operational parameters that can be adjusted during device programming include, but are not limited to ⁽¹¹⁾:
 - Rate Threshold Sensing for identifying VT/VF
 - The duration of an identified VT/VF that partitions non-sustained vs. sustained VT/VF
 - Antitachycardia pacing
 - Discrimination of SVT vs VT
 - T-wave and lead-related oversensing
- Device programming is indicated when one or more of the operational parameters are causing excessive battery depletion ⁽⁶⁾
- Device programming is also indicated when new permanent changes were done during the last device evaluation or deemed necessary after a recent remote interrogation.

Indications related to Remote Monitoring ⁽⁷⁾

- For patients with devices that permit remote monitoring, alert parameters for cardiac events should be optimized to the patient's unique pathophysiology during office visit. Accordingly, device programming may be indicated if the device is over- or under-reporting actionable cardiac events and/or shock therapies.
- For patients with ILR, Programming is indicated when there is frequent under sensing and/or oversensing. Alerts relating to actionable cardiac events, electrograms should be immediately reviewed to exclude misdiagnosis

Other Considerations

- Defibrillation threshold (DFT) testing for SCD, including for unique lead configurations,

may be appropriate at the time of device implantation or generator replacement. ⁽¹¹⁾
Examples of changeable parameters include shock vectors and timing.

Limitations

- When a patient is monitored both during clinic visits and trans-telephonically or remotely, the combined frequency of monitoring will be considered in evaluating the reasonableness of the frequency of monitoring services received by the patient.
- There are no frequency guidelines available for programming of Life Vest after initial set up.

CODING AND STANDARDS

Codes

Device Interrogation: 93261, 93288, 93289, 93290, 93291, 93292, 93293, 93294, 93295, 93296, 93297, 93298, 93724, G2066

Device Programming: 93260, 93279, 93280, 93281, 93282, 93283, 93284, 93285, 93640, 93641, 93644, 93745

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

1. **Cardiac Implantable Electrical Device (CIED):** An implanted device that either monitors, or regulates the heart rate, rhythm, or function. These devices include permanent pacemakers (PPM), implantable cardioverter-defibrillators (ICD), and implantable loop recorders (ILR).
2. **AICD/CRT-D, PPM/CRT-P/Subcutaneous ICD interrogation:** Measurement of previously programmed parameters including but not limited to, battery voltage, lead capture and sensing function, heart rhythm, absence, or presence of therapy for

ventricular tachyarrhythmias. Once the device battery longevity is reaching effective replacement indicator (ERI) or once it has reached end of life (EOL) the device will create an alert for replacement.

3. **Automatic implantable cardioverter defibrillator (AICD) or implantable cardioverter defibrillator (ICD):** Electronic device designed to detect and treat life-threatening tachyarrhythmia or brady-arrhythmias. The device consists of a pulse generator and electrodes for sensing, pacing and defibrillation.
4. **Cardiac Resynchronization Therapy-Defibrillators (CRT-D) and Cardiac Resynchronization Therapy-Pacemakers (CRT-P):** Cardiac device with multiple leads for defibrillation and cardiac pacing, capable of pacing and sensing function in the right atrium and both ventricles of the heart. Resynchronization of left ventricular depolarization is achieved by coordinating the excitation of the septum and the lateral wall, improving LV efficiency.
5. **Implantable loop recorder (ILR):** Patient- and auto-activated monitoring system that records ECG tracings and is indicated for patients who experience transient symptoms that suggest a cardiac arrhythmia. The physician utilizes a programmer to retrieve, display, and print data.
6. **ILR interrogation:** Downloading previously programmed parameters and the heart rate and rhythm during recorded episodes from both patient-initiated, and device detected events, when present.
7. **Life Vest/Wearable Defibrillator (WCD) Interrogation:** Previously programmed parameters, battery status, and the heart rate and rhythm during recorded episodes from both patient-initiated, and device detected events, when present.
8. **Life Vest/Wearable Defibrillator (WCD):** Worn by patients with medical issues that place them at risk for sudden cardiac death (SCD). Use of the wearable ICD (WCD) permits time to assess a patient's long-term arrhythmic risk and to determine if permanent ICD implantation is appropriate. It continuously monitors the patient's heart rate and, if a life-threatening heart rhythm is detected, delivers a shock intended to restore normal heart rhythm. ⁽⁹⁾ Current WCDs have embedded remote monitoring capability, allowing clinicians to monitor data downloaded from a patient's WCD. The patient downloads through the base station/battery charger. The device is connected via Bluetooth, signals are encrypted and sent wirelessly via cellular networks to the secure network website where it is archived for review. ⁽¹²⁾
9. **Pacemaker:** Medical device which uses electrical impulses, delivered by electrodes in contact with heart muscle, to regulate the heart rate when the normal pacemaker is too slow or there is a block in the electrical conduction system.
10. **Remote Interrogation (RI):** Remote evaluation of CIEDs using a wand-based radiofrequency platform to transfer data from patient's device to a home transceiver, then via telephone (analog phone line or cellular wireless data network) to a central repository. ⁽⁶⁾
11. **Remote Monitoring (RM):** Remote evaluation of CIEDs using automated platform by set radiofrequency transmissions sent wirelessly to a transceiver (located near the patient) then to central repository by analog landline or wireless data networks. Minimal information includes battery status, lead integrity, and arrhythmic events. ⁽⁶⁾

12. **Subcutaneous ICD:** (pulse generator) is implanted under the skin on the side of the chest below the arm pit. The pulse generator is connected to the electrode which is implanted under the skin from the device pocket along the rib margin to the breastbone with the use of the insertion tool. There are no electrodes/leads placed on (epicardial) or in (endocardial) the heart.
13. **Trans telephonic Monitoring (TTM):** Remote evaluation of CIEDs by analog transmission over a telephone line. Very limited information is available, and this method of monitoring has largely been supplanted by remote monitoring and interrogation. ⁽⁶⁾
14. **Leadless Pacemaker:** A self-contained medical device that includes pacemaker electronics and battery that is inserted directly into right side of the heart without the need for a surgical pocket and pacemaker leads. ⁽¹³⁾
15. **Physiologic Data Interrogation:** Some devices are equipped to provide information related to the patient's volume status. The Optivolt™ system uses transthoracic impedance calculated between the CIED's endocardial lead and pulse generator to reflect blood volume and lung water. This has yielded mixed clinical results. Multicenter trials have calculated positive predictive values ranging from 38.1% to 60% for the worsening of systolic heart failure. Another device using a remotely monitored implantable pulmonary artery hemodynamic sensor was tested in a large, randomized trial. Its utilization was shown to reduce HF hospitalization by 37%. ⁽⁶⁾
16. **Device Programming** (is a non-invasive process that allows the physician to set, or modify, the operational parameters of the implanted cardiac device. Examples of Device Programming include:
 - For AICD, SICD, CRT-D, CRT-P, and PPM:
 - Documented manual iterative temporary or permanent changes of capture and sensing thresholds.
 - Changes in the pacing output of a pacing lead, heart rhythm, upper and lower heart rates, sensor rate response, AV intervals, pacing voltage, pulse duration, sensing value and checking battery voltage.
 - In addition to these programming parameters, ventricular tachycardia detection and therapies are programmed based on device interrogation when medically necessary.
 - For an ILR:
 - Tachycardia and bradycardia rate adjustment based on interrogation when medically necessary.
 - For a Life Vest/Wearable Defibrillator:
 - Sensing thresholds and ventricular tachycardia detection and defibrillation therapies based on device interrogation when medically necessary. Note, there are no pacing capabilities in a Life Vest, and Programming is usually done during the initial setup of the device.
17. **Defibrillator Threshold (DFT) Test** - It is an integral part of implantable cardioverter-defibrillator implantation. It is usually performed at the time of initial implantation or after generator replacement. It involves testing of the device and leads by arrhythmia

induction and termination by delivering shock therapy through programmed parameters.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AICD: Automatic Implantable Cardiac Defibrillator

AUC: appropriate use criteria

AV: Atrioventricular

CIEDs: Cardiovascular Implantable Electronic Devices

CIEM: Cardiovascular Implantable Electronic Monitoring

CRT-D: Cardiac Resynchronization Therapy with ICD

CRT-P: Cardiac Resynchronization Therapy with Pacemaker

DFT: Defibrillation Threshold

ECG: electrocardiogram

EOL: end of life

ERI: elective replacement indicator

ICD: Implantable Cardioverter Defibrillator

ILR: Implantable Loop Recorder

PPM: Permanent Pacemaker

RI: Remote Interrogation

RM: Remote Monitoring

SCD: sudden cardiac death

SICD: Subcutaneous Implantable Cardioverter Defibrillator

TTM: Transtelephonic Monitoring

VF: Ventricular Fibrillation

VT: Ventricular Tachycardia

WCD: Wearable Cardiac Defibrillator

SUMMARY OF EVIDENCE

2023 HRS/EHRA/APHRS/LAHRs expert consensus statement on practical management of the remote device clinic ⁽⁷⁾

Study Design: This is an expert consensus statement developed by the Heart Rhythm Society (HRS) in partnership with the European Heart Rhythm Association (EHRA), the Asia Pacific Heart Rhythm Society (APHRS), and the Latin American Heart Rhythm Society (LAHRS). It provides comprehensive guidance for managing remote monitoring clinics for patients with cardiovascular implantable electronic devices (CIEDs).

Target Population: The document is intended for cardiac electrophysiologists, allied professionals, and hospital administrators involved in managing remote monitoring clinics for patients with CIEDs.

Key Factors:

- The document addresses remote monitoring clinic staffing, appropriate clinic workflows, patient education, and alert management.
- It provides evidence-based recommendations impacting all aspects of remote monitoring services.
- The document identifies gaps in current knowledge and provides guidance for future research directions.

HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices ⁽⁶⁾

Study Design: This is an expert consensus statement developed by the Heart Rhythm Society (HRS) in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), the Pediatric and Congenital Electrophysiology Society (PACES), and the Asia Pacific Heart Rhythm Society (APHRS). It focuses on remote interrogation and monitoring for cardiovascular implantable electronic devices (CIEDs).

Target Population: The document is intended for healthcare providers involved in the management of patients with CIEDs.

Key Factors:

- The document provides recommendations for remote interrogation and monitoring, including the clinical benefits, follow-up optimization, patient safety, and device surveillance.
- It discusses the roles and responsibilities of the remote monitoring team members, data management, and reimbursement, legal, and privacy considerations.
- The document emphasizes the importance of structured follow-up and the integration of remote monitoring into clinical practice.

2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing ⁽¹¹⁾

Study Design: This is an expert consensus statement developed by the Heart Rhythm Society (HRS) in partnership with the European Heart Rhythm Association (EHRA), the Asia Pacific Heart Rhythm Society (APHRS), and the Latin American Heart Rhythm Society (LAHRS). It provides guidance on optimal implantable cardioverter-defibrillator (ICD) programming and testing.

Target Population: The document is intended for healthcare providers involved in the management of patients with ICDs.

Key Factors:

- The document addresses bradycardia mode and rate programming, tachycardia detection programming, tachycardia therapy programming, and intraprocedural testing of defibrillation efficacy.
- It provides evidence-based recommendations for optimizing ICD programming to improve patient outcomes and reduce inappropriate therapies.
- The document highlights the importance of individualized programming based on patient-specific clinical conditions

ANALYSIS OF EVIDENCE

Shared Findings:

- Remote Monitoring Benefits: All three documents emphasize the benefits of remote monitoring in improving patient outcomes, reducing hospital visits, and early detection of device malfunctions.
- Patient Satisfaction: High patient satisfaction and improved quality of life are common themes in both Ferrick et al 2023 and Slotwiner et al 2015.
- Reduction in Inappropriate Shocks: Both Slotwiner et al 2015 and Wilkoff et al 2016 highlight the importance of reducing inappropriate ICD shocks.

Conclusion:

In summary, while all three documents highlight the benefits of remote monitoring and the importance of reducing inappropriate shocks, they differ in their focus areas and the level of detail provided in programming recommendations and future research directions.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none"> This guideline replaces Evolent Clinical Guideline 7277 for Device (PPM, AICD, CRT-D, Subcut-ICD, ILR) Programming This guideline replaces Evolent Clinical Guideline 7278 for Device Interrogation

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolut Clinical Guideline 7259 for Aortic Root, Ascending Aorta and Aortic Arch Surgery

Guideline Number: Evolut_CG_7259	<u>Applicable Codes</u>	
<i>"Evolut" refers to Evolut Health LLC and Evolut Specialty Services, Inc.</i> <i>© 2011 - 2026 Evolut. All rights Reserved.</i>		
Original Date: April 2011	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Ascending Aortic Open or Endovascular Surgery.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

General Considerations

For *elective* procedures notes must demonstrate that the member has been involved in a shared decision-making process involving the provider as well as relevant physicians to determine the optimal medical, endovascular, and open surgical therapies. This process should be reflected in notes provided. It is understood that those indications listed below with a “*” may be appropriate if the procedure is performed by an experienced surgeon in a multidisciplinary aortic team.

INDICATIONS ⁽⁶⁾

Aortic Root and Ascending Thoracic Aneurysm

NOTE: Requests for concomitant subclavian, innominate, or carotid artery bypass should be approved as well as CPT codes referencing Access sites, or adjunctive endovascular procedures

- Ruptured aneurysms irrespective of etiology.
- Sporadic Aneurysms:
 - ≥ 5.5 cm
 - < 5.5 cm with growth rate of ≥ 0.3 cm/y in 2 consecutive years or ≥ 0.5 cm in one year
 - ≥ 5.0 cm *
 - ≥ 5.0 cm undergoing repair or replacement of a tricuspid aortic valve
 - ≥ 4.5 cm undergoing repair or replacement of an aortic bicuspid valve *
 - > 5.0 cm undergoing repair or replacement of bicuspid valve
 - ≥ 5.0 cm concomitant with cardiac surgery for indications other than aortic valve repair or replacement
 - In patients with a height more than 1 standard deviation above or below the mean who have an asymptomatic aneurysm of the aortic root or ascending aorta and a maximal cross-sectional aortic area/height ratio of ≥ 10 cm²/m *
 - In patients who have either an aortic size index of ≥ 3.08 cm/m² or an aortic height index of ≥ 3.21 cm/m² *
- Nonsyndromic Aneurysm and no identifiable genetic cause
 - Timing and size are informed by known aortic diameters at the time of aortic dissection and/or thoracic aortic aneurysm repair in an affected family member
 - ≥ 5.0 cm when there is no information on aortic diameters at the time of dissection or aneurysm repair in affected family members, and there are no high-risk features for adverse aortic events
 - ≥ 4.5 cm, no identifiable genetic cause, high risk aortic events, or who are undergoing cardiac surgery for other indications provided aortic repair
- Syndromic heritable thoracic aortic disease (HTAD)
 - Marfan Syndrome
 - ≥ 5.0 cm
 - ≥ 4.5 cm with increased risk of dissection *:
 - Family history of aortic dissection
 - Rapid aortic growth (≥ 0.3 cm/year)
 - Diffuse aortic root and ascending aortic dilation

- Marked vertebral arterial tortuosity
 - In patients with an aortic root area (cm²) to patient height (m) ratio of ≥ 10 *
 - < 5 cm but who are candidates for valve sparing root replacement and have a very low surgical risk *
- Loeys-Dietz, Ehlers-Danlos, Turner Syndromes and Other Genetic Variants
 - The surgical threshold for prophylactic replacement should be informed by the specific genetic variant, aortic diameter, aortic growth rate, extra aortic features, family history, patient age and sex, patient and physician's preference and experience, and must be discussed fully in the notes provided.

Thoracic Arch Aneurysms

ANY of the following:

- ≥ 5.5 cm asymptomatic with low operative risk
- Symptoms attributable to the aneurysm and the member is at low or intermediate operative risk
- Concurrent with an ascending aortic aneurysm repair
- Concurrent with an elephant trunk procedure or replacement of the descending thoracic aorta

Acute Aortic Syndromes

Type A Aortic Dissection, Intramural Hematoma (IMH) and Penetrating Aortic Ulcer (PAU)

- Open surgical repair, Endovascular, or Hybrid Aortic Repair should be approved for hyperacute or acute pathology unresponsive to supportive medical therapy
- Procedures will be approved if a member is readmitted with new symptoms or evolving limb, organ or life-saving complications.
- If surgery is not performed and aneurysm results, treatment of the aneurysm will follow the guidelines for Aneurysms listed above

Blunt Traumatic Thoracic Aortic Injury (BTTAI)

- Open surgical repair, Endovascular, or Hybrid Aortic Repair should be approved for Grade 3 to 4 BTTAI and is not dependent on any variable.
- Grade 2 BTTAI with **ANY** high-risk imaging features:
 - Posterior mediastinal hematoma more > 10 mm
 - Lesion to normal aortic diameter ratio more > 1.4
 - Mediastinal hematoma causing mass-effect
 - Pseudocoarctation of the aorta

- Large left hemothorax
- Ascending aortic, aortic arch, or great vessel involvement
- Aortic arch hematoma

Other Conditions

- Takayasu and Giant cell Aortitis
 - Patients in remission with aortic and branch vessel complications e.g. transient ischemic attack (TIA), stroke, limb ischemia
- Surgery to remove and/or replace infected aorta or aortic grafts
- Surgery to treat aortic tumors
- Bicuspid Aortic Valve

CODING AND STANDARDS

Codes

33530, 33858, 33859, 33863, 33864, 33866

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Dilation of the ascending aorta (Thoracic Aortic Aneurysms (TAA)) is often detected during other cardiovascular imaging. Ascending aortic graft surgery is an excision and surgical replacement of the most proximal portion of the diseased thoracic aorta with a graft.

Definitions

- **Acute** is 1-14 days since onset of symptoms whereas **Hyperacute** is >24 hours since onset of symptoms.

- **Endograft** is a preconstructed graft that is inserted via a remote access site. There are commercial variants where the manufacturers' Instructions For Use (IFU) should be followed. There are surgeon modified grafts but these should only be used in institutions where the graft has been approved by an Institutional Review Board (IRB) or in a Government approved clinical trial.
- **Favorable anatomy for TEVAR** is anatomy that is consistent with the Instructions for Use (IFU) of the endograft that will be inserted.
- **Heritable Thoracic Aortic Disease (HTAD)** is an aortic condition related to a genetic or heritable condition some of which associated with multisystem features (considered syndromic HTAD) or others with abnormalities limited to the aorta with or without its branches (known as nonsyndromic HTAD). Examples include Marfan, Loeys-Dietz, Turner and Ehlers-Danlos syndromes, Familial Thoracic aortic aneurysms, and possibly bicuspid aortic valve.
- **High risk** is a member who has significant comorbidities increasing the risk of death, renal failure, stroke, or spinal ischemia and paraplegia.
- **Low risk** is a member who does not have significant comorbidities.
- **Intramural hematoma** in the wall of the artery without an identifiable communication between the true and false lumens. It is characterized by hyperdense, crescent-shaped hemorrhage within they wall best seen on non-contrast enhanced computed tomography.
- **Penetrating aortic ulcer (PAU)** is an atherosclerotic lesion that penetrates the internal elastic lamina of the aortic wall. It was also referred to as ulcer-like projections. It is often associated with IMH.
- **Unfavorable anatomy for TEVAR** is anatomy that would not be suitable for the IFU of any commercially available endograft.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AUC: Appropriate Use Criteria

BTTAI: Blunt Traumatic Thoracic Aortic Injury

CPT: Current Procedural Terminology

CTA: Computed Tomographic Angiography

HTAD: Heritable Thoracic Aortic Disease

IFU: Instructions For Use

IMH: Intramural Hematoma

IRB: Institutional Review Board

MRA: Magnetic Resonance Angiography

PAU: Penetrating Aortic Ulcer

TAA: Thoracic Aortic Aneurysm

TEVAR: Thoracic Endovascular Aortic Repair

TIA: Transient Ischemic Attack

SUMMARY OF EVIDENCE

2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease ⁽⁶⁾

Study Design: The guidelines were developed by the American Heart Association (AHA) and the American College of Cardiology (ACC) Joint Committee on Clinical Practice Guidelines. The recommendations are based on a comprehensive literature search conducted from January 2021 to April 2021, encompassing studies, reviews, and other evidence conducted on human subjects published in English from PubMed, EMBASE, the Cochrane Library, CINHL Complete, and other selected databases relevant to this guideline. Additional relevant studies published through June 2022 were also considered by the writing committee.

Target Population: The guidelines are intended for clinicians involved in the diagnosis, genetic evaluation, family screening, medical therapy, endovascular and surgical treatment, and long-term surveillance of patients with aortic disease across its multiple clinical presentation subsets (i.e., asymptomatic, stable symptomatic, and acute aortic syndromes). The recommendations apply to patients with or at risk of developing cardiovascular disease, with a focus on medical practice in the United States but relevant to patients worldwide.

Key Factors

- **Recommendations:** The guidelines update previously published AHA/ACC guidelines on thoracic aortic disease, peripheral artery disease, and bicuspid aortic valve disease with new evidence. New recommendations addressing comprehensive care for patients with aortic disease have been developed, emphasizing shared decision-making and the importance of institutional interventional volume and multidisciplinary aortic team expertise.
- **Imaging Techniques:** The guidelines provide detailed recommendations on aortic imaging techniques, including computed tomography (CT), magnetic resonance imaging (MRI), echocardiography, and ultrasound, to determine the presence and progression of aortic disease.
- **Surgical and Endovascular Management:** The guidelines discuss the timing and types of surgical and endovascular interventions for aortic aneurysms, acute aortic syndromes, and other aortic conditions. They emphasize the importance of multidisciplinary aortic

teams and high-volume centers for optimizing treatment outcomes.

- **Medical Management:** The guidelines include recommendations for medical therapy, including antihypertensive medications, statins, smoking cessation, and antiplatelet therapy, to manage aortic disease and reduce the risk of adverse aortic events.
- **Surveillance:** The guidelines provide recommendations for surveillance imaging after aortic repair to monitor for complications and progression of residual aortic pathology

ANALYSIS OF EVIDENCE

Aortic Root Surgery

Findings:

- **Aortic Valve Resuspension:** In patients with acute type A aortic dissection and a partially dissected aortic root but no significant aortic valve leaflet pathology, aortic valve resuspension is recommended over valve replacement.
- **Aortic Root Replacement:** In patients with extensive destruction of the aortic root, a root aneurysm, or a known genetic aortic disorder, aortic root replacement is recommended with a mechanical or biological valved conduit. Valve-sparing root repair may be reasonable in selected patients who are stable and when performed by experienced surgeons in a Multidisciplinary Aortic Team.

Ascending Aorta Surgery

Findings:

- **Open Distal Anastomosis:** In patients with acute type A aortic dissection undergoing aortic repair, an open distal anastomosis is recommended to improve survival and increase false-lumen thrombosis rates.
- **Hemiarch Repair:** In patients with acute type A aortic dissection without an intimal tear in the arch or a significant arch aneurysm, hemiarch repair is recommended over more extensive arch replacement.
- **Extended Aortic Repair:** In patients with acute type A aortic dissection and a dissection flap extending through the arch into the descending thoracic aorta, an extended aortic repair with antegrade stenting of the proximal descending thoracic aorta may be considered to treat malperfusion and reduce late distal aortic complications.

Aortic Arch Surgery

Findings:

- **Symptoms and Surgical Intervention:** In patients with an aortic arch aneurysm who have symptoms attributable to the aneurysm and are at low or intermediate operative risk, open surgical replacement is recommended.
- **Diameter Thresholds:** In patients with an isolated aortic arch aneurysm who are asymptomatic and have a low operative risk, open surgical replacement at an arch diameter of ≥ 5.5 cm is reasonable.

- **Hemiarch Replacement:** In patients undergoing open surgical repair of an ascending aortic aneurysm, if the aneurysmal disease extends into the proximal aortic arch, it is reasonable to extend the repair with a hemiarch replacement.
- **Elephant Trunk Procedure:** In patients undergoing open surgical repair of an aortic arch aneurysm, if the aneurysmal disease extends into the proximal descending thoracic aorta, an elephant trunk procedure may be considered

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> ● Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> ● Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices ● Reduced General Consideration section and edited text for clarity throughout ● Added risks of aortic dissection for Marfan syndrome in Indication section
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1097 for Ascending Aortic Graft Surgery <ul style="list-style-type: none"> ○ Guideline name was changed to Aortic Root, Ascending Aorta and Aortic Arch Surgery ● Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage



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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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4. Hendel RC, Lindsay BD, Allen JM, et al. ACC Appropriate Use Criteria Methodology: 2018 Update. *J Am Coll Cardiol*. 2018;71(8):935-948. doi:10.1016/j.jacc.2018.01.007
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Evolent Clinical Guideline 7260 for Automated Ambulatory Blood Pressure Monitoring

Guideline Number: Evolent_CG_7260	<u>Applicable Codes</u>	
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Original Date: November 2014	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Automated Ambulatory Blood Pressure Monitoring (ABPM).

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR AUTOMATED AMBULATORY BLOOD PRESSURE MONITORING ⁽⁶⁾

- Suspected white-coat hypertension:
 - Grade I hypertension (systolic blood pressure (SBP) is 140-159 mmHg and/or diastolic blood pressure (DBP) is 90-99 mmHg) on office BP (blood pressure) measurement
 - Marked office BP elevation without hypertension-mediated organ damage (HMOD)

- 130 mmHg < untreated SBP < 160 mmHg or 80 mmHg < untreated DBP < 100 mmHg ⁽⁷⁾
- Suspected masked hypertension:
 - High-normal office BP
 - Normal office BP in individuals with HMOD or at high total cardiovascular risk
 - Untreated office BPs consistently between 120 mmHg and 129 mmHg for SBP or between 75 mmHg and 79 mmHg for DBP ⁽⁷⁾
- In treated individuals:
 - Confirmation of uncontrolled and true resistant hypertension (defined as SBP is \geq 140 mmHg or DBP is \geq 90 mmHg despite being on maximally guideline-directed medical therapy (GDMT) with various causes of pseudo-resistant hypertension and secondary hypertension excluded)
 - Evaluation of 24-hour BP control (especially in high-risk patients)
 - Evaluating symptoms indicating hypotension (especially in older patients)
 - Suspected postural or postprandial hypotension
- Exaggerated BP response to exercise
- Considerable variability in office BP measurements
- Assessment of nocturnal BP and dipping status (e.g. sleep apnea, chronic kidney disease (CKD), diabetes, endocrine hypertension, or autonomic dysfunction). Repeating ABPM is necessary for reproducibility
- Patients incapable or unwilling to perform reliable home BP monitoring (HBPM), or anxious with self-measurement
- Pregnancy
- As periodic monitoring for confirmation of white-coat hypertension or masked hypertension in untreated or treated individuals to timely identify sustained hypertension or new HMOD
- As periodical follow-up for HMOD assessment in patients with true resistant hypertension to monitor kidney function and serum potassium levels

Note: The recommended time interval between measurements should be 20 minutes during day and night to minimize the risk of missing day or night periods. ⁽⁷⁾

CODING AND STANDARDS

Codes

93784, 93786, 93788, 93790

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Ambulatory blood pressure monitoring (ABPM) involves the use of a non-invasive device which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by the physician.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ABPM: Ambulatory blood pressure monitoring

BP: Blood pressure

CKD: Chronic kidney disease

DBP: Diastolic blood pressure

GDMT: Guideline-directed medical therapy

HBPM: Home blood pressure monitoring

HMOD: Hypertension-mediated organ damage

SBP: Systolic blood pressure

SUMMARY OF EVIDENCE

2023 ESH Guidelines for the management of arterial hypertension The Task Force for the management of arterial hypertension of the European Society of Hypertension ⁽⁶⁾

Study Design: This document presents the 2023 European Society of Hypertension (ESH) Guidelines for the management of arterial hypertension. It is a comprehensive guideline developed by a Task Force of 59 experts from various European countries, representing multiple medical specialties. The guidelines were developed after a thorough review of new studies in hypertension and related areas, with a focus on real-world studies and randomized controlled trials (RCTs).

Target Population: The guidelines are intended for adults with hypertension, including specific recommendations for different demographic groups such as children, adolescents, young adults, older persons, and women. It also addresses hypertension in various clinical conditions and comorbidities.

Key Factors:

- **Pathophysiology:** The guidelines discuss the genetic and environmental factors contributing to hypertension, including the role of the renin-angiotensin-aldosterone system (RAAS), autonomic regulation, and inflammation.
- **Diagnosis:** Recommendations for the classification of hypertension, BP measurement techniques, and the use of out-of-office BP monitoring (ABPM and HBPM) are provided.
- **Management:** The guidelines emphasize lifestyle interventions, pharmacological treatment, and the importance of achieving BP targets. Specific recommendations are made for different patient populations and clinical scenarios.
- **Follow-Up:** The importance of regular follow-up and monitoring of BP control, adherence to treatment, and the management of resistant hypertension are highlighted.

2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults ⁽⁷⁾

Study Design: This document is the 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. It was developed by a writing committee consisting of clinicians, cardiologists, epidemiologists, and representatives from various professional organizations. The guidelines are based on a systematic review of the literature and evidence from RCTs and observational studies.

Target Population: The guidelines are intended for adults with high blood pressure, including those with comorbid conditions such as cardiovascular disease (CVD), chronic kidney disease (CKD), diabetes mellitus (DM), and others.

Key Factors:

- **BP Classification:** The guidelines redefine high BP and provide new thresholds for the diagnosis and management of hypertension.
- **Risk Assessment:** The use of the ACC/AHA Pooled Cohort Equations to estimate 10-

year risk of atherosclerotic cardiovascular disease (ASCVD) is recommended to guide treatment decisions.

- **Nonpharmacological Interventions:** Emphasis is placed on lifestyle modifications such as weight loss, dietary changes (e.g., DASH diet), sodium reduction, potassium supplementation, physical activity, and moderation of alcohol intake.
- **Pharmacological Treatment:** Recommendations for the use of antihypertensive medications, including specific drug classes and combination therapies, are provided. The guidelines also address the management of hypertension in patients with comorbid conditions.
- **Follow-Up:** The importance of regular follow-up and monitoring of BP control, adherence to treatment, and the management of resistant hypertension are highlighted.

ANALYSIS OF EVIDENCE

Shared Findings ^(6,7):

Both guidelines emphasize the importance of accurate BP measurement, the role of lifestyle interventions, and the need for individualized treatment plans. They also highlight the significance of regular follow-up and monitoring to ensure effective BP control and reduce the risk of CVD and other complications.

Conclusion ^(6,7)

In summary, while both guidelines share common goals and recommendations, they differ in their emphasis on certain aspects of hypertension management and the specific details of their recommendations.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> ● Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> ● Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices ● No clinical changes ● Removed codes description ● Adjusted applicable lines of business – Medicare Advantage checked

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1336 Automated Ambulatory Blood Pressure Monitoring • Updated indications for Automated Ambulatory Blood Pressure Monitoring • Removed Special Note and Limitation sections • Updated references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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REFERENCES

1. Bonow RO, Douglas PS, Buxton AE, et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *J Am Coll Cardiol*. 2011;58(14):1517-1538. doi:10.1016/j.jacc.2011.07.007
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Evolent Clinical Guideline 7261 for Device (AICD, CRT and/or Pacemaker) Battery Replacement

Guideline Number: Evolent_CG_7261	<u>Applicable Codes</u>	
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Original Date: January 2025	Last Revised Date: May 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for device (AICD, CRT, and/or Pacemaker) battery replacement.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS

Battery Replacement

- Recent interrogation shows battery voltage in elective replacement indicator range or end of life indicator range (may differ by device type and manufacturer)

Lead Replacement

- Lead repositioning/replacement/removal may be performed when there is evidence of

lead malfunctioning on recent interrogation or if a lead recall has been issued

Device Relocation

- Repositioning/relocation of the skin pocket for the device may be performed in the presence of infection, the development of overlying skin erosion/tissue necrosis, if any other anatomical factor prevents the device from properly functioning, or if device migration has resulted in significant patient discomfort

CODING AND STANDARDS

Codes

33210, 33211, 33214, 33215, 33216, 33217, 33218, 33220, 33222, 33223, 33227, 33228, 33229, 33233, 33234, 33235, 33236, 33237, 33238, 33241, 33244, 33262, 33263, 33264, 93640, 93641

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

The automatic implantable cardioverter defibrillator (AICD) is an electronic device designed to detect and treat life-threatening tachyarrhythmia's or brady arrhythmias. The device consists of a pulse generator and electrodes for sensing, pacing, and defibrillation. Subcutaneous ICDs do not include transvenous leads and cannot provide pacing for bradycardia.

The AICD is checked periodically, amongst other parameters, for battery voltage. Once its longevity reaches the effective replacement indicator (ERI) or once it has reached end of life (EOL) the defibrillator will generate an alert for replacement.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AICD: Automatic internal cardiac defibrillator

AUC: Appropriate use criteria

CRT: Cardiac resynchronization therapy

EOL: End of life

ERI: Effective replacement indicator

POLICY HISTORY

Date	Summary
May 2025	<ul style="list-style-type: none"> • Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices • Removed Special Note section • No clinical changes • Adjusted applicable lines of business –Medicare Advantage checked
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM Cardio 1144 Automatic Implantable Cardioverter Defibrillator Battery Replacement • This guideline replaces UM Cardio 1145 Pacemaker Battery Replacement

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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REFERENCES

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Evolut Clinical Guideline 7262 for Diagnostic Electrophysiologic Testing

Guideline Number: Evolut_CG_7262	<u>Applicable Codes</u>	
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Original Date: January 2025	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

For the performance of diagnostic electrophysiologic testing in patients with symptoms suspected to be caused by disturbances in the conduction or maintenance of cardiac rhythm.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR DIAGNOSTIC ELECTROPHYSIOLOGIC TESTING (EPS) ⁽⁶⁾

Sustained Narrow Complex Tachycardia ⁽⁷⁾

- To establish the mechanism of the rhythm when ablation is planned, including patients with preexcitation syndromes or Wolff-Parkinson-White (WPW)

Frequent Ventricular Extrasystoles, Couplets, and Nonsustained Ventricular Tachycardia (NSVT) ^(8,9)

- Patients with other risk factors for future arrhythmic events, such as a low left ventricular ejection fraction (LVEF), positive signal-averaged electrocardiogram (ECG), and non-sustained ventricular tachycardia (VT) on ambulatory ECG recordings in whom EPS will be used for further risk assessment and for guiding therapy in patients with inducible VT
- Patients with highly symptomatic, monomorphic premature ventricular complexes (PVCs), couplets, and NSVT who are considered as potential candidates for catheter ablation
- In patients with a prior myocardial infarction (MI), LVEF < 40%, and nonsustained VT, performance of an EPS with programmed ventricular stimulation is indicated for selecting suitable candidates for implantable cardioverter-defibrillator (ICD) implantation

Sustained Ventricular Tachycardia ⁽⁸⁾

Structurally normal hearts

- Sustained monomorphic ventricular tachycardia in patients with structurally normal hearts:
 - Before catheter ablation, an EPS should be offered to symptomatic patients with documented sustained monomorphic ventricular tachycardia

Structurally abnormal hearts

- Sustained monomorphic ventricular tachycardia in patients with structurally abnormal hearts:
 - EPS should be performed preceding catheter ablation in patients with monomorphic sustained VT in candidates suitable for catheter ablation, typically in the same procedure
 - EPS is indicated in patients with wide QRS complex tachycardia in whom correct diagnosis is unclear after analysis of available ECG tracings, when knowledge of the correct diagnosis is required for patient care
 - EPS with standby catheter ablation should be considered in patients who develop VT following valvular surgery to identify and cure potential bundle branch re-entry VT
 - After catheter or surgical ablation of ventricular tachycardia, in patients with implantable defibrillators (ICD), programmed extra stimulation to assess the inducibility of clinically significant VT may be performed using the ICD when clinically indicated

After Surgical VT Ablation ⁽⁹⁾

- EPS may be performed in patients who have undergone surgical ablation of ventricular tachycardia, to determine inducibility of ventricular tachycardia and risk stratification for ICD implantation

Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) ⁽⁸⁾

- In patients with ARVC and documented sustained and hemodynamically well-tolerated ventricular tachycardia, EPS may be performed if ablation of the arrhythmia is planned. (Hemodynamically poorly tolerated VT in this entity is an indication for ICD, and EPS should **not** be done)
- EPS may be performed in patients with ARVC and symptoms suggestive of malignant arrhythmia (palpitations and syncope) or NSVT when no documentation of sustained monomorphic VT exists.

NOTE: EPS is not indicated in **asymptomatic** patients with ARVC without documented sustained VT, due to the poor predictive value of programmed extrastimulation in these patients.

NOTE: Diagnostic EPS has no place in the evaluation of patients with documented **polymorphic ventricular tachycardia (PMVT)**. Similarly, EPS is not indicated in the evaluation of patients with Catecholaminergic Polymorphic Ventricular Tachycardia, although it may be considered for the ablation of the PVCs that initiate PMVT

Syncope ⁽¹⁰⁾

- EPS is indicated for the evaluation of syncope when noninvasive testing has been unrevealing; relevant clinical scenarios include:
 - Syncope with suspected sinus node dysfunction
 - Patients with syncope and left bundle branch block or bifascicular block (right bundle branch block and left anterior fascicular or left posterior fascicular block)
 - Patients with syncope and ischemic or other structural heart disease in which ventricular tachycardia is a potential cause for symptoms
 - Syncope in patients employed in high-risk occupations (airline pilots, bus drivers, police, firefighters, etc.)
 - Syncope immediately preceded by palpitations
 - Syncope or resuscitated sudden death in patients with preexcitation pattern on the ECG (WPW)
 - Unexplained syncope

Conduction Disturbances ^(11,12)

EPS is indicated for:

- Symptomatic Type 2 AV block, to determine the site of block. (since permanent pacemaker implantation is indicated for block in or below the bundle of His)
- Adult patients with myotonic muscular dystrophy, even in the absence of surface ECG abnormalities, to identify patients with a prolonged HV interval (>70 msec) in whom permanent pacemaker implantation should be considered
- Risk stratification of asymptomatic preexcitation (WPW pattern on ECG) to determine the refractory period of the accessory pathway and/or the shortest pre-excited R-R

interval in atrial fibrillation

- Ventricular programmed extrastimulation may be performed in patients with cardiac sarcoidosis with a LVEF >35%, for risk stratification and consideration of ICD therapy

Coronary Artery Disease ⁽⁸⁾

- EPS is indicated in patients with CAD with remote MI with symptoms suggestive of ventricular tachyarrhythmias, including palpitations, presyncope, and syncope
- EPS may be performed in patients with ischemic cardiomyopathy with LVEF 35-40% and non-sustained ventricular tachycardia (since inducible VT/VF is Class 1 indication for ICD)

Wide Complex Tachycardia ⁽⁸⁾

- EPS is indicated in evaluation of wide complex tachycardias, including left bundle branch block, to establish the mechanism of the rhythm disturbance and to aid in determining correct management (i.e., to exclude pre-excited tachycardia in WPW or Mahaim-related tachycardia mimicking ventricular tachycardia), and to determine eligibility for catheter ablation or ICD implantation

Congenital Heart Disease ⁽¹¹⁾

- EPS is indicated in adults with congenital heart disease and life-threatening arrhythmias or resuscitated sudden cardiac death, when the cause for the event is unknown or there is potential for therapeutic intervention (ablation) at the time of the electrophysiological procedure
- EPS may be performed in patients with congenital heart disease with unexplained syncope with impaired ventricular function (LVEF <50%). In these patients, in the absence of a defined and reversible cause, ICD implantation is considered reasonable.
- EPS may be used for risk stratification in adults with Tetralogy of Fallot (TOF) **who have additional risk factors** for sudden cardiac death, defined as left ventricular systolic or diastolic dysfunction, nonsustained VT, QRS duration of ≥180 msec, and extensive right ventricular scarring.
- EPS with or without catheter ablation can be useful in diagnostic evaluation of adults with Ebstein anomaly and ventricular preexcitation but without supraventricular tachycardia ⁽¹³⁾
- EPS (and catheter ablation, if needed) is reasonable for adults with Ebstein anomaly before surgical intervention on the tricuspid valve even in the absence of preexcitation or supraventricular tachycardia ⁽¹³⁾

Note: EPS/programmed extrastimulation is **not indicated** in the evaluation of Long QT Syndromes, Short QT Syndromes, or Early Repolarization. Studies of EPS in Brugada Syndrome have demonstrated poor correlation between inducibility and prognosis, and EPS is not recommended

In survivors of cardiac arrest not due to a reversible cause, ICD implantation without prior performance of an EPS is appropriate, with rare exceptions.

CODING AND STANDARDS

Codes

93609, 93613, 93619, 93620, 93621, 93622, 93642, 93644, 93655

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Invasive Cardiac Electrophysiology Studies (EPS) involve the use of multielectrode catheters introduced into the cardiac chambers, and typically positioned in the right atrium, right ventricle, region of the A-V Node and the Bundle of His, and frequently the coronary sinus.

Several vascular access sites are typically needed, and may include the femoral vein(s), jugular vein(s), subclavian vein(s) and the brachial vein(s). Under certain circumstances, access to the left heart may require either transseptal puncture or a retrograde approach via the femoral artery across the aortic valve. In these cases, systemic anticoagulation is mandated.

After initial recordings of baseline electrograms from the catheters, programmed extrastimulation of the various cardiac chambers may be undertaken to study conduction characteristics, physiology of the conduction system, and in an attempt inducibility of clinically relevant tachydysrhythmias. Provocation with drugs that affect electrical conduction, including atropine, isoproterenol, and adenosine, is commonly utilized to enhance the inducibility of abnormal heart rhythms.

EPS is typically performed in conjunction with catheter ablation of previously documented tachydysrhythmias, to confirm the mechanism of the rhythm disturbance and to facilitate its induction, which is required to identify the critical site(s) for ablation.

Definitions

Sustained Tachycardia: tachycardia lasting 20 seconds or longer, or requiring cardioversion because of hemodynamic collapse

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ARVC: Arrhythmogenic right ventricular cardiomyopathy

A-V Node: Atrioventricular node

AUC: Appropriate use criteria

CAD: Coronary Artery Disease

ECG: Electrocardiogram

EPS: Electrophysiology studies

ICD: Implantable Cardioverter-Defibrillator

LVEF: Left ventricular ejection fraction

MI: Myocardial Infarction

NSVT: Non-sustained ventricular tachycardia

PMVT: Polymorphic ventricular tachycardia

PVC: Premature ventricular complexes

QRSd: Duration of the QRS complex

TOF: Tetralogy of Fallot

VT: Ventricular tachycardia

VF: Ventricular fibrillation

WPW: Wolff-Parkinson-White

SUMMARY OF EVIDENCE

2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death ⁽⁸⁾

Study Design: This document is a clinical practice guideline developed by the American College of Cardiology, American Heart Association, and Heart Rhythm Society. It is based on systematic methods to evaluate and classify evidence, including literature searches, randomized controlled trials, registries, nonrandomized comparative and descriptive studies, case series, cohort studies, systematic reviews, and expert opinion.

Target Population: The guideline is intended for adults who have ventricular arrhythmias (VA) or are at risk for sudden cardiac death (SCD), including those with diseases and syndromes associated with a risk of SCD from VA.

Key Factors: The guideline covers various aspects such as epidemiology, mechanisms of VA, general evaluation of patients, therapies for treatment or prevention of VA, acute management of specific VA, ongoing management of VA and SCD risk related to specific disease states, and special considerations for catheter ablation.

PACES/HRS Expert Consensus Statement on the Recognition and Management of Arrhythmias in Adult Congenital Heart Disease ⁽¹¹⁾

Study Design: This document is an expert consensus statement developed by the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS), endorsed by several other organizations. It is based on formal literature reviews, expert opinion, and evidence-based recommendations.

Target Population: The statement focuses on adults with congenital heart disease (CHD) and arrhythmias, including those with various types of CHD such as atrial septal defects, Ebstein anomaly, tetralogy of Fallot, and Fontan procedure.

Key Factors: The document addresses the recognition and management of arrhythmias in adults with CHD, including epidemiology, delivery of care, evaluation and diagnosis, medical therapy, catheter ablation, bradyarrhythmias and pacemakers, sudden cardiac death and ICDs, cardiac resynchronization therapy, surgical options, and recommendations for electrophysiologic study prior to adult CHD surgery.

Recommendations for the use of electrophysiological study: Update 2018 ⁽⁶⁾

Study Design: This document is a review article that provides updated recommendations for the use of electrophysiological studies (EPS) in clinical practice. It is based on a comprehensive review of relevant articles, clinical practice guidelines, and position statements from various organizations.

Target Population: The recommendations are intended for patients with different types of cardiac pathologies, including sinus node dysfunction, atrioventricular block, bundle branch block, narrow and wide QRS complex tachycardias, inherited primary arrhythmia syndromes, progressive cardiac conduction disease, early repolarization syndrome, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, left ventricular noncompaction, muscular dystrophies, ischemic heart disease, infiltrative diseases,

congenital heart disease, unexplained syncope, survivors of cardiac arrest, undocumented palpitations, and candidates for or carriers of cardiac implantable electronic devices.

Key Factors: The document discusses the role of EPS in diagnosing and managing various cardiac conditions, guiding catheter ablation procedures, and establishing indications for cardiac device implantation. It provides detailed recommendations for each cardiac disease/group of diseases, including the rationale, evidence, and specific indications for EPS.

ANALYSIS OF EVIDENCE

Shared Findings ^(6,8,11):

- Importance of EPS: All three documents emphasize the importance of EPS in diagnosing and managing cardiac arrhythmias and conduction disorders. EPS is considered a valuable tool for evaluating patients with various cardiac conditions and guiding therapeutic interventions.
- Role in Risk Stratification: EPS is highlighted as a key method for risk stratification in patients with ventricular arrhythmias and sudden cardiac death risk. It helps identify patients who may benefit from implantable cardioverter-defibrillators (ICDs) and other preventive measures.
- Guidance for Catheter Ablation: EPS is recognized as essential for guiding catheter ablation procedures, particularly in patients with complex arrhythmias and structural heart disease.

Conclusion ^(6,8,11):

In summary, while all three documents highlight the importance of EPS in diagnosing and managing cardiac arrhythmias, they differ in their target populations, specific recommendations, and focus areas. Al-Khatib et al 2018 and Khairy et al 2014 provide general guidelines and consensus statements, whereas Muresan et al 2019 offers detailed recommendations for a wide range of cardiac conditions.

POLICY HISTORY

Date	Summary
December 2025	<ul style="list-style-type: none"> ● Added “for adults with Ebstein anomaly” to bullet under Congenital Defects, for purposes of clarification ● Added the following CPT Codes to reflect Evolent prior authorization scope: 93609, 93613, 93621, 93622, 93655
July 2025	<ul style="list-style-type: none"> ● Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices

Date	Summary
	<ul style="list-style-type: none"> • Added new indications in congenital heart disease section • Adjusted applicable lines of business – Medicare Advantage checked • Updated references • Added a Summary of Evidence and Analysis of Evidence
December 2024	<ul style="list-style-type: none"> • This guideline replaces Evolent Utilization Management Cardio Policy 1101: Cardiac Electrophysiology Study without Arrhythmia Induction • This guideline replaces Evolent Utilization Management Cardio Policy 1139: Cardiac Electrophysiology Study with Arrhythmia Induction • This guideline replaces Evolent Utilization Management Cardio Policy 1143: Non-Invasive Programmed Stimulation of AICD

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guideline 7263 for Cardiac Resynchronization Therapy

Guideline Number: Evolent_CG_7263	<u>Applicable Codes</u>	
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Original Date: January 2026	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

This guideline describes the medical necessity for cardiac resynchronization therapy (CRT). Indications for CRT for patients are based upon left ventricular (LV) ejection fraction (LVEF), QRS duration, New York Heart Association (NYHA) functional class (presence or absence of symptoms) and need for ventricular pacing regardless of etiology (ischemic or non-ischemic cardiomyopathy). ⁽¹⁾

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽²⁻⁶⁾

INDICATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY (CRT)

Cardiomyopathy

NOTE: The following indications only apply to patients:

- Who have been on guideline-directed medical therapy (GDMT) for 3 months or
- Who have been on GDMT and are 40 days after myocardial infarction (MI), or
- With implantation of pacing or defibrillation device for special indications (class indicates NYHA functional class)

Class I Through Class IV ^(1,7)

- Ischemic cardiomyopathy, LVEF $\leq 35\%$, QRS ≥ 150 ms, left bundle branch block (LBBB), Sinus Rhythm (**AUC Score 7-9**)
- Nonischemic cardiomyopathy, LVEF $\leq 35\%$, QRS ≥ 150 ms, LBBB, Sinus Rhythm (**AUC Score 7-9**)

Class II Through Class IV ^(1,7)

- Ischemic and non-ischemic cardiomyopathy, LVEF $\leq 35\%$, QRS 120-149 ms, LBBB, Sinus Rhythm (**AUC Score 7**)
- Ischemic and non-ischemic cardiomyopathy, LVEF $\leq 35\%$, QRS ≥ 150 ms, non-LBBB (**AUC score 6**)
- Nonobstructive hypertrophic cardiomyopathy (HCM), LVEF $< 50\%$, LBBB, CRT therapy for symptom reduction

Class III Through Class IV ^(1,8)

- Ischemic cardiomyopathy, LVEF $\leq 30\%$, QRS ≥ 150 ms, non-LBBB, Sinus Rhythm (**AUC Score 7**)
- Nonischemic cardiomyopathy, LVEF $\leq 35\%$, QRS ≥ 150 ms, non-LBBB, Sinus Rhythm (**AUC Score 7**)
- Ischemic and non-ischemic cardiomyopathy, LVEF 31-35%, QRS ≥ 150 ms, non-LBBB, Sinus Rhythm (**AUC Score 7**)

Special Circumstances when CRT ICD may be implanted after < 3 months GDMT

- Criteria are met, based on a pacing indication, for a non-elective implantable cardioverter defibrillator (ICD) or pacemaker and in the face of the low likelihood of improvement in symptoms and adequate recovery of LVEF, despite less than 3 months GDMT for heart failure or < 40 days post myocardial infarction or 3 months post revascularization, criteria for CRT are otherwise met. This avoids a second implantation procedure within less than 3 months ^(1,9)

Special Situations: Independent/Regardless of NYHA Heart Failure Class

- Patients with an indication for ventricular pacing, a LVEF $\leq 50\%$, and high degree atrioventricular (AV) block or are expected to be paced more than 40% of the time; this

includes patients with atrial fibrillation ^(1,8)

- Patients with Atrial fibrillation and LVEF $\leq 35\%$ who requires ventricular pacing or otherwise meets CRT criteria; **AND** AV nodal ablation or pharmacologic rate control will allow nearly 100% ventricular pacing with CRT ⁽⁷⁾
- For patients with atrial fibrillation and LVEF $\leq 50\%$, if a rhythm control strategy fails and ventricular rates remain rapid despite medical therapy, atrioventricular nodal ablation with implantation of a CRT device is reasonable ⁽⁷⁾
- As CRT has not been studied in transthyretin amyloid cardiomyopathy (ATTR-CM), those with heart failure with reduced ejection fraction (HFrEF) should follow guidelines for Class II-Class IV indications

Not Indicated

- NYHA class I or II and non-LBBB pattern with QRS duration < 150 ms, ⁽¹⁾except as in Special Situations section above
- NYHA class I through IV with QRS duration < 120 ms ⁽¹⁾
- Comorbidities and/or frailty expected to limit survival with good functional capacity to < 1 year ^(1,7)
- Active bloodstream infection
- Reversible causes are present such as toxic-, metabolic- or tachycardic-mediated cardiomyopathy, would require reassessment once the situation is corrected
- Cardiogenic shock or symptomatic hypotension while in stable baseline rhythm

Adult Congenital Heart Disease (CHD)

Class I Through Class IV

- Systemic ventricle with EF $\leq 35\%$, intrinsic narrow QRS complex, and undergoing new device placement or replacement with anticipated requirement for significant ($> 40\%$) ventricular pacing (**AUC Score 7-8**). ⁽¹⁰⁾
- Systemic ventricle with EF $> 35\%$, intrinsic narrow QRS complex, and undergoing new device placement or replacement with anticipated requirement for significant ($> 40\%$) ventricular pacing (**AUC Score 6**). ⁽¹⁰⁾
- Any CHD, regardless of specific ejection fraction, with progression of systolic systemic ventricular dysfunction and/or ventricular dilation, *and who are undergoing other cardiac surgery*, (particularly if thoracotomy is anticipated to be needed for LV pacing), with a QRS complex ≥ 150 ms (**AUC Score 6**) ⁽¹⁰⁾

Class II Through Class IV

- Systemic LVEF $\leq 35\%$, sinus rhythm and wide QRS complex ≥ 150 ms ⁽¹⁰⁾
- Any CHD, wide QRS complex ≥ 150 ms due to a complete RBBB, with a severe sub-pulmonary right ventricle (RV) dysfunction and dilatation despite interventions to

decrease RV volume overload ⁽¹⁰⁾

- Patients with single ventricle or systemic right ventricle with an LVEF \leq 35% with QRS complexes \geq 120 ms with either RBBB or LBBB morphology ⁽¹⁰⁾

Class IV

- Severe ventricular dysfunction, and would otherwise be candidates for heart transplantation or mechanical circulatory support ⁽¹⁰⁾

Not Indicated

- Patients whose co-morbidities and/or frailty limit survival with good functional capacity to < 1 year ⁽¹⁰⁾
- Patients with a narrow QRS complex (< 120 ms) without major electrical activation delay within the failing ventricle ⁽¹⁰⁾

CODING AND STANDARDS

Codes

33221, 33224, 33225, 33231, 33241, 33249

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

CRT, which paces the left and right ventricle in rapid sequence, also known as biventricular pacing, improves coordination of left ventricular contraction in the presence of a wide QRS complex in systolic heart failure, by simultaneously pacing the interventricular septum and the left lateral wall.

CRT improves cardiac function and quality of life, and it decreases cardiac events and mortality among appropriately chosen patients. In the proper patient population, improved survival in

patients with CRT can be greater than that provided by implantable cardioverter-defibrillator (ICD) insertion alone.

Guiding principles in the consideration of CRT:

- NYHA class is an important qualifying factor, with candidacy based on functional class, EF, and QRS duration.
- Bundle branch block or intraventricular conduction delay should be persistent, not rate related. ⁽¹⁾
- GDMT should have been in place continuously for at least 3 months after initiation of therapy for cardiomyopathy or 40 days post myocardial infarction to allow recovery of LVEF. This 3-month time period is “reset” if a revascularization is performed in the interim. Reversible causes (e.g., ischemia) should be excluded. ⁽⁷⁾
- The patient should have expected survival with a reasonably good functional status for more than 1 year. ⁽¹⁾

Definitions

NYHA Class Definitions ⁽¹⁾

- Class I: No limitation of functional activity. Ordinary physical activity does not cause symptoms of HF
- Class II: Slight limitation of activity. Comfortable at rest but ordinary physical activity results in symptoms of HF
- Class III: Marked limitation of activity. Comfortable at rest but less than ordinary activity causes symptoms of HF
- Class IV: Unable to continue any physical activity without symptoms of HF, or symptoms of HF at rest

Heart Block Definitions ⁽¹¹⁾

- First Degree: All atrial beats are conducted to the ventricles, but with a delay of > 200 ms
- Second Degree: Intermittent failure of conduction of single beats from atrium to ventricles.
 - Type I: Conducted beats have variable conduction times from atrium to ventricles.
 - Type II: Conducted beats have uniform conduction times from atrium to ventricles.
 - Advanced: Two or more consecutive non-conducted beats (premature atrial beats might not normally be conducted).
- Third Degree: No atrial beats are conducted from atrium to ventricle.

Guideline-Directed (or Optimal) Medical Therapy in Heart Failure ⁽⁷⁾

- Angiotensin converting enzyme inhibitor (ACE-I), angiotensin receptor blocker (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)

- Beta blocker

Other options/considerations for GDMT ⁽⁷⁾

- Addition of loop diuretic for all NYHA class II – IV patients
- Addition of hydralazine and nitrate for persistently symptomatic African Americans, NYHA class III-IV
- Addition of an aldosterone antagonist, provided eGFR is ≥ 30 ml/min/1.73 m² and K⁺ < 5.0, NYHA class II-IV
- Not required for consideration of CRT: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁵⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ACE-I: Angiotensin converting enzyme inhibitor

ARB: Angiotensin receptor blocker

ARNI: Combined angiotensin receptor inhibitor and neprilysin inhibitor

ATTR-CM: Transthyretin Amyloid Cardiomyopathy

AV: Atrioventricular

CAD: Coronary artery disease, same as ischemic heart disease

CHD: Congenital heart disease

CRT: Cardiac resynchronization therapy (also known as biventricular pacing)

EF: Ejection Fraction

eGFR: Estimated glomerular filtration rate

GDMT: Guideline-Directed Medical Therapy

HCM: Hypertrophic Cardiomyopathy

HF: Heart failure

HFrEF: Heart failure with reduced ejection fraction

ICD: Implantable cardioverter-defibrillator

LBBB: Left bundle branch block

LV: Left ventricular/left ventricle

LVEF: Left ventricular ejection fraction

MI: Myocardial infarction

ms: Milliseconds

NYHA: New York Heart Association

RBBB: Right bundle branch block

RV: Right ventricle

SUMMARY OF EVIDENCE

2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure ⁽⁷⁾

Study Design: This document is a clinical practice guideline for the management of heart failure, developed by the American College of Cardiology/American Heart Association/Heart Failure Society of America Joint Committee on Clinical Practice Guidelines. It is based on a comprehensive literature search conducted from May 2020 to December 2020, including studies, reviews, and other evidence from human subjects published in English.

Target Population: The guideline is intended for clinicians to prevent, diagnose, and manage patients with heart failure. It provides patient-centric recommendations for the treatment of heart failure, aiming to improve quality of care and align with patients' interests.

Key Factors: The guideline includes recommendations for the prevention, diagnosis, and management of heart failure, based on contemporary evidence. It covers various aspects such as stages of heart failure, classification by left ventricular ejection fraction, diagnostic algorithms, epidemiology, causes, initial and serial evaluation, use of biomarkers, genetic evaluation, cardiac imaging, invasive evaluation, remote monitoring, exercise and functional capacity testing, risk scoring, and management strategies for different stages of heart failure.

Arrhythmias in congenital heart disease ⁽¹⁰⁾

Study Design: This document is a position paper on arrhythmias in congenital heart disease, developed by the European Heart Rhythm Association, Association for European Pediatric and Congenital Cardiology, and the European Society of Cardiology Working Group on Grown-up Congenital Heart Disease, endorsed by HRS, PACES, APHRS, and SOLAECE. It is based on a detailed literature review and expert consensus.

Target Population: The position paper addresses arrhythmias in patients with congenital heart disease, focusing on young adults with congenital heart defects who suffer from arrhythmias due to the underlying defect or as a sequela of interventional or surgical treatment.

Key Factors: The paper discusses the management of arrhythmias in congenital heart disease, including pharmacological treatment, catheter ablation, and device therapy. It highlights the importance of understanding the individual pathological anatomy and physiology, as well as the natural history and long-term prognosis of patients. The document covers various types of

arrhythmias, their substrates, work-up, acute assessment, collaboration between specialists, general assessment, imaging requirements, specific arrhythmia types, and management strategies.

ACC/AHA/ASE/HFSA/HRS/SCAI/SCCT/SCMR 2025 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy, and Pacing ⁽¹⁾

Study Design: This document is an appropriate use criteria (AUC) for implantable cardioverter-defibrillators (ICD), cardiac resynchronization therapy (CRT), and pacing, developed by the American College of Cardiology Solution Set Oversight Committee, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. It is based on a comprehensive review of common clinical scenarios and expert consensus.

Target Population: The AUC document addresses patients who are candidates for ICD, CRT, and pacing therapies, including those with heart failure, genetic conditions, structural heart disease, and other related conditions.

Key Factors: The document provides a detailed review of 335 clinical scenarios related to ICD, CRT, and pacing, including secondary prevention, primary prevention, comorbidities, generator replacement, dual-chamber ICD, totally subcutaneous ICD, CRT, LVAD, heart transplantation, cardiac contractility modulation, leadless pacing, and conduction system pacing. It categorizes the scenarios as "Appropriate," "May Be Appropriate," or "Rarely Appropriate" based on the potential benefits and risks of device implantation.

ANALYSIS OF EVIDENCE

Shared Findings ^(1,7,10)

- **Effectiveness:** All three documents recognize the effectiveness of CRT in managing heart failure and arrhythmias. They emphasize the importance of CRT in improving patient outcomes, particularly in those with reduced ejection fraction and heart failure symptoms.
- **Patient Selection:** The importance of selecting appropriate patients for CRT is highlighted across all documents. They stress the need for careful evaluation of patient characteristics, including ejection fraction, heart failure symptoms, and arrhythmia history.
- **Guideline Recommendations:** The documents provide guideline-based recommendations for CRT, ensuring that clinicians have access to evidence-based practices for managing heart failure and arrhythmias.

Conclusion ^(1,7,10)

In summary, these articles collectively provide a robust framework for managing various cardiovascular conditions, each contributing unique insights and recommendations tailored to specific patient populations and clinical scenarios.

POLICY HISTORY

Date	Summary
December 2025	<ul style="list-style-type: none"> Fixed symbol typo under “Class II Through Class IV” heading
July 2025	<ul style="list-style-type: none"> Reviewed to reconcile dates, no substantive changes made
June 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
April 2025	<ul style="list-style-type: none"> This guideline merges two Evolent guidelines with identical clinical criteria: ECG 7263-01 for Cardiac Resynchronization Therapy and ECG 320 for Cardiac Resynchronization Therapy into Evolent Clinical Guideline 7263 for Cardiac Resynchronization Therapy <ul style="list-style-type: none"> This guideline also merges Procedure Codes from these two Evolent guidelines Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices Updated CRT indication for cardiomyopathy per recent societal appropriate use criteria Corrected and added other CRT indications for congenital heart disease Adjusted applicable lines of business – Medicare Advantage checked

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance



that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7264 for Renal Angiography and Intervention

Guideline Number: Evolent_CG_7264	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for renal angiography and those required interventions after angiography.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR RENAL ANGIOGRAPHY

Renal Artery Stenosis

Note: 2013 ACCF/AHA ⁽⁶⁾ and 2024 ESC ⁽⁷⁾ recommend noninvasive DUS (duplex ultrasonography) as the first-line imaging, followed by CTA (eGFR is ≥ 60 mL/min) and/or MRA (eGFR is ≥ 30 mL/min) to establish the diagnosis of renal artery stenosis (RAS). When the clinical index of suspicion is high and the results of noninvasive studies are inconclusive, 2013 ACC/AHA recommends catheter angiography, while 2017 ESC ⁽⁸⁾ recommends DSA (digital subtraction angiography).

- Hypertension:
 - Uncontrolled arterial hypertension ($> 140/90$ mm Hg) ⁽⁹⁾ despite being on maximal tolerated guideline-directed medical therapy (≥ 3 antihypertensive medications), defined as resistant hypertension ^(6,7)
 - Accelerated (defined as sudden and persistent worsening of controlled hypertension) and malignant hypertension (defined as hypertension with evidence of acute end-organ damage) ⁽⁶⁾
 - Onset of hypertension at < 30 years old ^(6,7)
 - Onset of severe hypertension at > 55 years old, with evidence of CKD (chronic kidney disease) and cardiac failure ^(6,7)
- Renal Dysfunction
 - New azotemia or worsening renal function after administration of an ACE inhibitor or ARB agent ^(6,7)
 - Unexplained atrophic kidney (7 to 8 cm) or size discrepancy greater than 1.5 cm between kidneys ^(6,7)
 - Unexplained renal dysfunction, including individuals starting renal replacement therapy (dialysis or renal transplantation) ^(6,7)
- Sudden and unexplained pulmonary edema, especially in azotemic patients ^(6,7)
- Multivessel coronary artery disease with no evidence of PAD at the time of arteriography ⁽⁶⁾
- Unexplained congestive heart failure or refractory angina ⁽⁶⁾

Fibromuscular Dysplasia ⁽¹⁰⁾

Note: CTA is the first-line imaging for suspected FMD for accurate differentiation of FMD from atherosclerotic renal artery stenosis. Contrast-enhanced magnetic resonance angiography (MRA) is the next option if CTA is contraindicated. When the results of CTA or MRA confirm the diagnosis of FMD, or when a clinical index of suspicion is high despite negative findings on CTA or MRA, catheter angiography should be considered for angioplasty and gradient obliteration assessment. Translesional pressure gradient measurement is also recommended for assessment of hemodynamic significance of stenosis, particularly in multifocal FMD, as well as post-angioplasty in both focal and multifocal FMD. ^(10,11)

- Onset of hypertension less than 30 years of age, especially women
- Accelerated, malignant, or grade 3 ($> 180/110$ mm Hg) hypertension
- Drug-resistant hypertension despite being on maximally tolerated GDMT (blood pressure target not achieved despite 3 drug-therapy at optimal doses including a diuretic)
- Unilateral small kidney without a causative urological abnormality
- Abdominal bruit in the absence of atherosclerotic disease or risk factors for atherosclerosis
- Suspected renal artery dissection or infarction

- Presence of FMD in at least one other vascular territory

INDICATIONS FOR RENAL ARTERY INTERVENTION

- Cardiac Disturbance Syndromes
 - Hemodynamically significant renal artery stenosis (RAS) and recurrent, unexplained congestive heart failure or sudden, unexplained pulmonary edema ⁽⁶⁾
 - Hemodynamically significant RAS and unstable angina ⁽⁶⁾
 - Flash pulmonary edema or acute coronary syndrome with hypertension and moderate RAS with resting translesional mean gradient of ≥ 10 mm Hg and/or severe RAS. **(AUC Score 9)** ⁽⁹⁾
 - Recurrent congestive heart failure with unilateral moderate RAS with resting translesional mean gradient of ≥ 10 mm Hg **(AUC Score 5)** ⁽⁹⁾
- Hypertension
 - Hemodynamically significant RAS and accelerated/resistant/malignant hypertension, or hypertension with an unexplained unilateral small kidney, or hypertension with intolerance to medication ⁽⁶⁾
 - Fibromuscular Dysplasia with early onset of accelerated/malignant/resistant hypertension ⁽¹¹⁾
 - Resistant hypertension (uncontrolled arterial hypertension despite being on maximal (≥ 3) tolerated medical therapy including diuretic) with evidence of bilateral or solitary severe RAS **(AUC Score 7)** ⁽⁹⁾
 - Resistant hypertension with evidence of unilateral severe RAS **(AUC Score 6)** ⁽⁹⁾
 - Resistant hypertension severe unilateral RAS and high-risk lesion or complex anatomy **(AUC Score 4)** ⁽⁹⁾
 - Nonproteinuric hypertension with unilateral renal artery disease ⁽¹¹⁾
- Kidney Dysfunction
 - Progressive chronic kidney disease (CKD) with bilateral ($>70\%$) RAS or a RAS in a solitary kidney ^(6,7)
 - Chronic renal insufficiency with unilateral RAS ($>70\%$) ^(6,7)
 - CKD Stage 4 with bilateral moderate RAS and resting mean translesion gradient of ≥ 10 mm Hg with kidney size > 7 cm in pole-pole length **(AUC Score 8)** ⁽⁹⁾
 - CKD Stage 4 and global renal ischemia (unilateral severe RAS with solitary kidney or bilateral severe RAS) without other explanation **(AUC Score 7)** ⁽⁹⁾
 - CKD class II with bilateral severe RAS **(AUC Score 5)** ⁽⁹⁾
 - CKD class III, stable for one year, with bilateral severe RAS **(AUC Score 5)** ⁽⁹⁾
- Hypertension and/or signs of renal dysfunction due to RAS caused by fibromuscular

dysplasia ⁽⁷⁾

- Evidence of progressive renal artery occlusion ⁽¹¹⁾
- Identifiable activation of renin-angiotensin system with hyperreninemia or with unilateral renal artery stenosis, lateralization of renal vein renin ⁽¹¹⁾
- Angiotensin-dependent glomerular filtration rate ⁽¹¹⁾
- Renal artery dissection; renal artery aneurysm and renal artery atherosclerosis greater than 50% in a transplanted kidney
- Special Populations ⁽¹¹⁾:
 - Transplant renal artery stenosis with or without calcineurin inhibitors
 - Episodic, circulatory congestion with bilateral atherosclerotic renovascular disease
 - Progressive loss of glomerular filtration rate with occlusive atherosclerotic renovascular disease and no other kidney disease (ischemic nephropathy)
 - Aortic disease with renovascular protection as part of endovascular repair
 - Left-ventricular assist device
 - Radiation-induced renovascular disease with clinical syndromes
 - Other diseases: e.g., Takayasu arteritis, extrinsic vascular compression
 - Pediatric patients with mid aortic syndrome or fibromuscular variants

Note: Atherosclerotic renovascular disease with **hemodynamically insignificant stenosis** do **not** benefit from vascular intervention when treated with optimal guideline-directed medical therapy (GDMT). Symptomatic Fibromuscular dysplasia (FMD)-related renovascular disease is warranted for consideration for renal balloon angioplasty procedure, followed by stenting in dissection management or balloon angioplasty failure. ^(8,11)

LIMITATIONS FOR RENAL ARTERY INTERVENTION ⁽⁹⁾

- Resistant hypertension and unilateral moderate RAS with a mean translesional gradient of < 10 mm Hg
- Progressive CKD stage 3 to stage 4 over six months with solitary or unilateral, severe RAS, with kidney size < 7 cm in pole-to-pole length
- Resistant hypertension with unilateral chronic total occlusion of the renal artery
- Blood Pressure (BP) ≥ 150/100 mm Hg on two medications (one diuretic) with severe unilateral RAS
- BP ≥ 150/100 mm Hg on one hypertensive agent with severe unilateral RAS
- Solitary or bilateral severe RAS with controlled BP and normal renal function
- CKD class II with unilateral severe RAS
- Bilateral or unilateral severe RAS with controlled BC and normal renal function

- Bilateral severe RAS with chronic end stage renal disease on hemodialysis > 3 months

CODING AND STANDARDS

Codes

Angiography: 36251, 36252, 75726

Intervention: 37236, 37237, 37246, 37247

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Renal angiography is X-ray study of blood vessels to the kidney. X-rays are taken while contrast dye is injected into a catheter (a tiny tube) that has been placed into the blood vessels of the kidneys to detect any signs of blockage, narrowing, or other abnormalities affecting the blood supply to the kidneys.

Renal Artery Angioplasty is an endovascular procedure to widen narrowed or obstructed renal arteries typically to treat arterial atherosclerosis. An empty, collapsed balloon, known as a balloon catheter, is passed over a wire into the narrowed locations and then inflated to a fixed size. The balloon forces expansion of the stenosis (narrowing) within the vessel and the surrounding muscular wall, opening up the blood vessel for improved flow, and the balloon is then deflated and withdrawn. A stent may or may not be inserted at the time of ballooning to ensure the vessel remains open.

Renovascular hypertension is one of many clinical syndromes of renovascular disease, derived most often from atherosclerosis, followed by FMD. Other less common causes include renal artery aneurysm, dissection, extravascular compression, infarction, mid aortic coarctation, partial or complete renal artery coverage by stent grafts, allograft inflow obstruction, and anatomic variants. ⁽¹¹⁾

Definitions

- Hemodynamically significant RAS is defined as either ⁽⁹⁾:

- Angiographic stenosis severity between 50-70% stenosis with resting or hyperemic mean pressure gradient ≥ 10 mm Hg
- Angiographic stenosis severity between 50-70% stenosis with resting or hyperemic systolic pressure gradient ≥ 20 mm Hg
- Angiographic stenosis severity between 50-70% stenosis with Renal Pd/Pa ≤ 0.8
- Angiographic stenosis severity with $\geq 70\%$ stenosis.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ACE: Angiotensin-converting enzyme

ARB: Angiotensin II receptor blockers

BP: Blood pressure

CKD: Chronic kidney disease

CTA: Computed tomography angiography

DUS: Duplex ultrasonography

DSA: Digital subtraction angiography

eGFR: Estimated glomerular filtration rate

FMD: Fibromuscular dysplasia

GDMT: Guideline-directed medical therapy

PAD: Peripheral artery disease

RAS: Renal Artery Stenosis

SUMMARY OF EVIDENCE

Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations) ⁽⁶⁾

Study Design: The guidelines are based on a compilation of recommendations from the 2005 and 2011 ACCF/AHA guidelines. The document does not present new evidence but repackages existing recommendations to provide a complete set of guidelines in a single resource.

Target Population: The guidelines target individuals at risk for or diagnosed with renal artery stenosis (RAS), including those with hypertension, chronic kidney disease, and other related conditions.

Key Factors: Diagnostic studies are recommended for patients with early-onset hypertension, severe hypertension, accelerated or malignant hypertension, new or worsening renal function after ACE inhibitor or ARB therapy, unexplained atrophic kidney, or sudden unexplained pulmonary edema. Revascularization may be considered for asymptomatic bilateral or solitary viable kidney with significant RAS and is reasonable for patients with significant RAS and hypertension, progressive chronic kidney disease, recurrent unexplained congestive heart failure, or unstable angina. Renal stent placement is indicated for ostial atherosclerotic RAS lesions, and balloon angioplasty with bailout stent placement is recommended for fibromuscular dysplasia lesions. Vascular surgical reconstruction is indicated for patients with fibromuscular dysplastic RAS with clinical indications for intervention, atherosclerotic RAS with clinical indications for intervention, and atherosclerotic RAS in combination with pararenal aortic reconstructions.

These guidelines provide a comprehensive approach to the diagnosis and treatment of renal artery stenosis, aiming to improve patient outcomes through evidence-based recommendations.

2024 ESC Guidelines for the management of peripheral arterial and aortic diseases ⁽⁷⁾

Study Design: The guidelines are developed by the task force on the management of peripheral arterial and aortic diseases of the European Society of Cardiology (ESC). The document is endorsed by several reputable organizations, including the European Association for Cardio-Thoracic Surgery (EACTS), the European Reference Network on Rare Multisystemic Vascular Diseases (VASCERN), and the European Society of Vascular Medicine (ESVM). The guidelines are based on a critical review and evaluation of published literature, including clinical trials and meta-analyses.

Target Population: The target population for these guidelines includes patients with peripheral arterial and aortic diseases, specifically those with renal artery disease. The guidelines address both atherosclerotic and non-atherosclerotic causes of renal artery stenosis (RAS), as well as special populations such as patients with fibromuscular dysplasia.

Key Factors: Duplex Ultrasound (DUS) is recommended as the first-line imaging modality for patients with suspicion of RAS. It provides high sensitivity and specificity for detecting significant stenosis. Catheter Angiography is considered the gold standard for diagnosing RAS, allowing for additional hemodynamic measurements.

Treatment Strategy: Revascularization should be considered in patients with atherosclerotic unilateral RAS (>70%) with high-risk features and signs of kidney viability, bilateral RAS, or RAS in a solitary kidney. It is also recommended for patients with hypertension and/or signs of renal dysfunction due to RAS caused by fibromuscular dysplasia.

SCAI appropriate use criteria for peripheral arterial interventions: An update ⁽⁹⁾

Study Design: The document discusses various studies, including prospective multicenter registries and randomized controlled trials (RCTs). One notable RCT mentioned is the CORAL

(Cardiovascular Outcomes in Renal Atherosclerotic Lesions) trial, which compared medical therapy alone to medical therapy combined with renal stenting.

Target Population: The studies primarily focus on patients with renal artery stenosis (RAS) and hypertension. The CORAL trial, for example, included patients with newly diagnosed renal artery stenosis and hypertension.

Key Factors: The document highlights improvements in systolic and diastolic blood pressure, renal function stabilization, and cardiac destabilization syndromes (heart failure and angina exacerbations) as benefits of renal artery stenting. The CORAL trial had limitations such as enrolling patients with moderate hypertension receiving only two antihypertensive medications and not requiring maximally tolerated doses. Hemodynamically severe renal artery stenosis is defined by specific pressure gradients and fractional flow reserve measurements. Meta-analyses show that fewer antihypertensive medications are required to achieve desired blood pressure reduction following renal artery revascularization.

ANALYSIS OF EVIDENCE

Analysis ^(6,7,9):

In summary, while all three articles agree on the importance of accurate diagnosis and medical management for RAS, they differ in their conclusions regarding the impact of revascularization on cardiovascular events and the preferred methods for revascularization. This analysis highlights the evolving understanding and approaches to managing renal artery disease.

Shared Conclusions:

- Importance of Accurate Diagnosis: All three articles emphasize the need for accurate diagnosis of RAS using non-invasive methods like DUS, CTA, and MRA, with catheter angiography reserved for inconclusive cases.
- Medical Management: They all highlight the role of medical management, particularly antihypertensive therapy, as a first-line treatment for RAS.
- Criteria for Revascularization: The articles agree on the criteria for revascularization, focusing on patients with bilateral RAS, RAS in a solitary kidney, and those with high-risk features.

Differing Conclusions

- Impact of Revascularization on Cardiovascular Events: Anderson 2013 and Mazzolai 2024 discuss the benefits of revascularization in improving blood pressure and renal function, while Klein 2017 notes that revascularization has not shown a significant impact on major adverse cardiovascular events.
- Preferred Revascularization Methods: Anderson 2013 and Mazzolai 2024 recommend renal stent placement and balloon angioplasty, with Mazzolai 2024 also suggesting open surgical revascularization for complex cases. Klein 2017 emphasizes the importance of GDMT before considering revascularization.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> This guideline replaces Evolent Clinical Guideline 7324 for Renal Angiography This guideline replaces Evolent Clinical Guideline 7325 for Renal Artery Intervention

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guideline 7265 for Cardiovascular Stress Test

Guideline Number: Evolent_CG_7265	<u>Applicable Codes</u>	
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Original Date: July 2011	Last Revised Date: July 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Cardiovascular Stress Test (walking exercise treadmill ECG test).

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR CARDIOVASCULAR STRESS TEST

Known or Suspected Coronary Artery Disease (CAD) ⁽⁶⁾

- Symptoms suggesting myocardial ischemia
 - When a non-cardiac explanation is provided for symptoms, no testing is required **(AUC Score 8)** ⁽⁶⁾
- Asymptomatic patient
 - Prior to initiation of an unsupervised exercise program, with or without known CAD

(AUC Score 7) ⁽⁶⁾

- Prior to cardiac rehabilitation **(AUC Score 7) ⁽⁶⁾**
- Syncope/presyncope
 - When initial evaluation suggests cardiovascular abnormalities **(AUC Score 7) ⁽⁶⁾**
- Arrhythmias
 - In patients with frequent PVCs (premature ventricular contraction) or non-sustained ventricular tachycardia **(AUC Score 7) ⁽⁶⁾**
 - Evaluation of patients with known or suspected exercise-induced arrhythmias ⁽⁷⁾
 - Evaluation of patients with suspected chronotropic incompetence ⁽⁸⁾
 - In patients with suspected long QT syndrome for diagnosis and therapy response ⁽⁹⁾
 - In selected first-degree relatives of patients with arrhythmogenic right ventricular cardiomyopathy ⁽⁹⁾
 - In first-degree relatives of subjects ≤ 40 years old who died suddenly and whose death could reasonably be attributed to unexplained sudden cardiac death (SCD), for comprehensive cardiac evaluation (including exercise stress testing) ⁽⁹⁾
 - Identification of appropriate settings in patients with rate-adaptive pacemakers ⁽⁷⁾
 - Evaluation of congenital complete heart block in patients considering increased physical activity or participation in competitive sports ⁽⁷⁾
- Hypertrophic Cardiomyopathy (HCM) ⁽¹⁰⁾
 - To determine functional capacity and to provide prognostic information as part of initial evaluation
- Valvular Disease
 - Aortic stenosis in asymptomatic patients with severe aortic stenosis (Stage C1) to assess physiological changes with exercise and to confirm the absence of symptoms ⁽¹¹⁾
 - Chronic aortic regurgitation ^(7,11):
 - with equivocal symptoms, to assess functional capacity and symptoms
 - to assess symptoms and functional capacity prior to participation in athletic activity
 - prognostic assessment before aortic valve replacement in asymptomatic or minimally symptomatic patients with left ventricular dysfunction
 - In asymptomatic women with severe valve disease (Stage C1) considering pregnancy ⁽¹¹⁾
- Coarctation of the Aorta ⁽¹²⁾
 - In adults, for exercise-induced hypertension
- Prior to Elective Non-Cardiac Surgery in asymptomatic patient ^(13–15)

- An intermediate- or high-risk surgery with one or more patient risk factors (see below), **AND** there has not been an ischemia evaluation within 1 year
 - Patient risk factors: history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and preoperative serum creatinine > 2.0 mg/dL
 - Surgical Risk:
 - High risk surgery: Aortic and other major vascular surgery, peripheral vascular surgery, anticipated prolonged surgical procedures associated with large fluid shifts and/or blood loss
 - Intermediate risk surgery: Carotid endarterectomy, head and neck surgery, intraperitoneal and intrathoracic surgery, orthopedic surgery, prostate surgery
 - Low risk surgery: Endoscopic procedures, superficial procedure, cataract surgery, breast surgery

LIMITATIONS FOR CARDIOVASCULAR STRESS TEST

- Abnormal ST changes on resting ECG, digoxin, left bundle branch block, Wolff-Parkinson-White pattern, ventricular paced rhythm (unless test is performed to establish exercise capacity and not for diagnosis of ischemia) ⁽¹⁶⁾
- Unable to achieve ≥ 5 METs or unsafe to exercise ⁽¹⁶⁾
- High-risk unstable angina or acute myocardial infarction, active acute coronary syndrome ⁽¹⁶⁾
- Uncontrolled heart failure ⁽¹⁶⁾
- Significant cardiac arrhythmias such as ventricular tachycardia, complete atrioventricular block or high risk for arrhythmias caused by QT prolongation ⁽¹⁶⁾
- Severe symptomatic aortic stenosis ⁽¹⁶⁾
- Severe systemic arterial hypertension (e.g., $\geq 200/110$ mmHg) ⁽¹⁶⁾
- Acute illness such as acute pulmonary embolism, acute myocarditis/pericarditis, and acute aortic dissection ⁽¹⁶⁾
- Routine periodic stress testing is not recommended in patients with chronic coronary artery disease (CCD) without clinical or functional status changes ⁽¹⁷⁾

CODING AND STANDARDS

Codes

93015, 93016, 93017, 93018

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Cardiovascular stress test is a test used to measure cardiovascular response to external stress through treadmill/bicycle exercise in a controlled clinical environment.

Cardiovascular stress tests compare the coronary circulation while the patient is at rest with the same patient's circulation observed during maximum physical exertion, showing any abnormal blood flow to the myocardium as depicted by the continuously monitored EKG/ECG. The results can also be interpreted as a reflection on the general physical condition of the test patient (blood pressure response and exercise tolerance).

Definitions

- Duke Exercise ECG Treadmill Score - Calculate risk from ECG Treadmill Score ⁽¹⁸⁾
 - The equation for calculating the Duke treadmill score (DTS) is: $DTS = \text{exercise time in minutes} - (5 \times \text{ST deviation in mm or } 0.1 \text{ mV increments}) - (4 \times \text{exercise angina score})$, with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting.
 - The score typically ranges from - 25 to + 15. These values correspond to low-risk (with a score of $\geq + 5$), intermediate risk (with scores ranging from - 10 to + 4), and high-risk (with a score of ≤ -11) categories.
- Global Risk of Cardiovascular Disease
 - Global risk of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to asymptomatic patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. High global risk by itself generally lacks scientific support as an indication for stress imaging. There are rare exemptions, such as patients requiring IC antiarrhythmic drugs, who might require coronary risk stratification prior to initiation of the drug.
 - CAD Risk—Low
 - 10-year absolute coronary or cardiovascular risk less than 10%.

- CAD Risk—Moderate
 - 10-year absolute coronary or cardiovascular risk between 10% and 20%.
- CAD Risk—High
 - 10-year absolute coronary or cardiovascular risk of greater than 20%.

Websites for Global Cardiovascular Risk Calculators* (19–23)

Risk Calculator	Link to Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have known CAD are already at high global risk and are not applicable to the calculators

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Guideline-Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

Acronyms/Abbreviations

CAD: Coronary artery disease

DTS: Duke treadmill score

EKG/ECG: Electrocardiogram

GDMT: Guideline directed medical therapy

HCM: Hypertrophic cardiomyopathy

MET: Metabolic equivalent

PVC: Premature ventricular contraction

SCD: Sudden cardiac death

SUMMARY OF EVIDENCE

ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease ⁽⁶⁾

Study Design: The study is a report by the American College of Cardiology (ACC) Solution Set Oversight Committee, in collaboration with several other cardiovascular societies. It updates the prior AUC for various cardiovascular imaging modalities, including radionuclide imaging, stress echocardiography, calcium scoring, coronary computed tomography angiography (CCTA), stress cardiac magnetic resonance (CMR), and invasive coronary angiography.

Target Population: The target population includes patients with known or suspected CCD, which encompasses stable ischemic heart disease (SIHD). The clinical scenarios cover both symptomatic and asymptomatic patients, with and without prior testing or revascularization.

Key Factors: The document outlines 64 clinical scenarios for the detection and risk assessment of CCD, drawn from common applications and current clinical practice guidelines. The clinical scenarios were rated by an independent panel using a modified Delphi process. Ratings were categorized as Appropriate (7-9), May Be Appropriate (4-6), or Rarely Appropriate (1-3).

2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death ⁽⁹⁾

Study Design: The guideline is based on a systematic review of evidence from various sources, including randomized controlled trials (RCTs), registries, nonrandomized comparative and descriptive studies, case series, cohort studies, systematic reviews, and expert opinion. The writing committee used evidence-based methodologies to formulate recommendations, focusing on the quality of scientific evidence and the magnitude and certainty of benefit in proportion to risk.

Target Population: The guideline is intended for adults who have ventricular arrhythmias (VA) or are at risk for sudden cardiac death (SCD), including those with diseases and syndromes associated with a risk of SCD from VA. It covers a wide range of conditions, including ischemic heart disease, nonischemic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, hypertrophic cardiomyopathy, myocarditis, cardiac sarcoidosis, neuromuscular disorders, and cardiac channelopathies.

Key Factors: Indications for ICD Implantation, secondary prevention for patients who survive sudden cardiac arrest (SCA) due to VA or experience hemodynamically unstable VT. Primary prevention for patients with reduced left ventricular ejection fraction (LVEF) due to ischemic or nonischemic cardiomyopathy. Management of VA in specific populations such as athletes, pregnant women, older patients with comorbidities, and patients with chronic kidney disease.

2024 AHA/ACC/AMSSM/HRS/PACES/SCMR Guideline for the Management of Hypertrophic Cardiomyopathy⁽¹⁰⁾

Study Design: This document is a guideline developed by the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines, in collaboration with several other medical societies. It includes recommendations based on a comprehensive literature search and evidence review.

Target Population: The guidelines focus on patients with hypertrophic cardiomyopathy, including adults, children, and adolescents. It addresses the diagnosis, risk assessment, and management of HCM, including the use of ICDs for SCD prevention.

Key Factors: The document highlights the importance of SCD risk assessment in HCM patients, including factors such as family history of SCD, maximal LV wall thickness, unexplained syncope, LV apical aneurysm, extensive LGE, and NSVT episodes. Recommendations for ICD placement in high-risk HCM patients consider individual clinical judgment, shared decision-making, and the presence of major risk factors. The guidelines discuss the selection of ICD devices, including single-chamber, dual-chamber, and subcutaneous ICDs, based on patient preferences and clinical needs. The document provides recommendations for the pharmacological and invasive treatment of symptomatic HCM patients, including the use of beta blockers, calcium channel blockers, myosin inhibitors, and septal reduction therapies.

ANALYSIS OF EVIDENCE

Analysis^(6,9,10):

While all three articles emphasize the importance of cardiovascular stress testing in diagnosing and managing cardiac conditions, they differ in their specific guidelines, patient populations, and

clinical scenarios. The articles highlight the diverse applications of stress testing in cardiology and the need for tailored guidelines based on specific clinical contexts.

Shared Conclusions:

- All three articles emphasize the significance of cardiovascular stress testing in diagnosing and managing various cardiac conditions. Stress testing is highlighted as a crucial tool for assessing myocardial ischemia, ventricular arrhythmias, and hypertrophic cardiomyopathy (HCM).
- The articles discuss various types of stress tests, including exercise treadmill testing, stress echocardiography, and stress cardiac magnetic resonance (CMR). These tests are used to evaluate different aspects of cardiac function and identify potential issues.
- Cardiovascular stress testing is commonly used for risk stratification in patients with known or suspected cardiac conditions. The tests help determine the severity of the condition and guide treatment decisions.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none">● No substantial clinical criteria changes● Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices● Added a Summary of Evidence and Analysis of Evidence● Updated references
December 2024	<ul style="list-style-type: none">● This guideline replaces UM CARDIO_1114 Cardiovascular Stress Test● Updated clinical indication, limitation and background sections● Removed Special Note section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7266 for Carotid Artery Stenting

Guideline Number: Evolent_CG_7266	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*
- *Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided*

Purpose

Indications for determining medical necessity for Carotid Artery Stenting.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS FOR CAROTID ARTERY STENTING BY TRANSFEMORAL (TFS) OR TRANSCAROTID REVASCULARIZATION (TCAR)

- Symptomatic carotid artery stenosis $\geq 50\%$ **AND** all of the following:

- Duplex ultrasound demonstrating the following ^(6,7):
 - Systolic velocity ≥ 125 cm/sec and internal carotid artery/common carotid artery (ICA/CCA) ratio ≥ 2 ⁽⁶⁾
- Computed tomography angiography (CTA) or magnetic resonance angiography (MRA), if not contraindicated, confirming $\geq 50\%$ stenosis and providing additional information about the aortic arch, and extra- and intra-cranial circulation. ^(6,7)
- Diagnostic cerebrovascular arteriogram confirming $\geq 50\%$ stenosis if CTA and MRA contraindicated ⁽⁶⁾
- Neurological assessment by a neurologist or NIH stroke scale (NIHSS) certified health professional
- Stenting should be performed no more than 14 days after the onset of symptoms for **ANY** of the following:
 - In a patient with moderate to high-risk concomitant medical conditions ⁽⁷⁾
 - In a patient with fibromuscular hyperplasia ^(8,9)
 - In patients with ischemic neurological symptoms that have not responded to antithrombotic therapy after acute carotid dissection ^(6,8)
 - By TFS in a patient with anatomical conditions that increase the risk of carotid endarterectomy or TCAR ^(10,11)
 - Neck stoma
 - Severe external radiation-induced skin and local tissue induration
 - Neck infection
 - Cervical instability or fixation
 - In a patient with significant tandem lesions
 - In a patient with disease extending above C2
- Asymptomatic carotid stenosis $> 70\%$
 - Stenting is performed in a low-risk patient
 - Duplex ultrasound demonstrating the following ^(6,7):
 - Systolic velocity ≥ 230 cm/sec and ICA/CCA ratio ≥ 4 and end diastolic velocity of ≥ 100 cm/sec ⁽⁶⁾
 - CTA or MRA, if not contraindicated, confirming $\geq 70\%$ stenosis and providing additional information about the aortic arch, and extra- and intra-cranial circulation ^(6,7)
 - After diagnostic cerebrovascular arteriogram if CTA and MRA contraindicated

LIMITATIONS FOR CAROTID ARTERY STENTING

- Stent(s) within 48 hours of a stroke ⁽⁷⁾
- Carotid stenosis < 50% ^(6,8)
- Chronic total occlusion of the targeted carotid artery ⁽⁸⁾
- Patients with severe disability caused by cerebral infarction that precludes preservation of useful function ⁽⁸⁾
- Patients with 50-99% stenoses who experience a disabling stroke (modified Rankin score ≥ 3), or whose area of infarction exceeds one third ($> 30\%$) of the ipsilateral middle cerebral artery territory, or who have altered consciousness/drowsiness ^(7,10)
- Asymptomatic patients with < 70% carotid stenosis ⁽⁸⁾
- Patients with asymptomatic FMD of a carotid artery, regardless of the severity of stenosis ⁽⁸⁾
- Patients with 70-99% asymptomatic carotid stenosis in order to prevent cognitive decline ⁽¹⁰⁾
- Patients presenting with carotid territory symptoms in the previous six months and who have < 50% stenosis ⁽¹⁰⁾
- Patients with carotid near occlusion and distal vessel collapse ⁽¹⁰⁾
- Staged or synchronous stent/CABG to prevent stroke in the presence of an asymptomatic unilateral 70-99% carotid stenosis ⁽¹⁰⁾
- Prophylactic carotid stent for an asymptomatic patient with 50-99% carotid stenosis undergoing a major non-cardiac surgical procedure ⁽¹⁰⁾
- Transfemoral stent in the presence of severe aortic calcification, atherosclerosis or tortuosity ⁽¹⁰⁾
- TCAR in the presence of a tracheal stoma, or ANY of the following ⁽¹¹⁾
 - Situation where local tissues are scarred and fibrotic from prior ipsilateral surgery or external beam radiotherapy
 - Lesion < 5 cm from the clavicle
 - Severe calcification
 - Local infection

CODING AND STANDARDS

Codes

37215, 37216

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- **Carotid stenting:** A procedure that opens clogged arteries to prevent or treat stroke. The carotid arteries are located on each side of the neck and are the main arteries supplying blood to the brain. The procedure involves temporarily inserting and inflating a tiny balloon where the carotid artery is clogged to widen the artery and placement of a small metal coil called a stent in the clogged artery. The stent helps prop the artery open and decreases the chance of it narrowing again.
- **Rankin Score:** The degree measurement of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability.
- **Shared decision process:** A member-provider interaction that must include a discussion of alternative treatments. The discussion includes complications, recurrent symptoms, and future reinterventions. The phrase "risks and alternatives have been described" is not sufficient
- **Transfemoral stent (TFS):** A stent inserted via a remote puncture of the femoral artery, and which involves traversing the aortic arch and which is usually supplemented by distal filter placement to prevent embolization
- **Transcarotid Revascularization (TCAR):** A process involves a small cutdown on the cervical common carotid artery and placing the stent during reversal of flow out of the brain to prevent distal embolization

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6

- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: Coronary artery bypass graft

CAS: Carotid artery stenting

CEA: Carotid endarterectomy

CTA: Computed tomography angiography

FMD: Fibromuscular dysplasia

GDMT: Guideline-directed medical therapy

MRA: Magnetic resonance angiography

NCD: National Carrier Determination

PTA: Percutaneous Transluminal Angioplasty

RPVI: Registered Physician in Vascular Interpretation

RVT: Registered Vascular Technologist

TCAR: Transcarotid Revascularization

TFS: Transfemoral stent

TIA: Transient ischemic attack

SUMMARY OF EVIDENCE

2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease ⁽⁸⁾

Study Design: The guideline is based on a thorough review of the literature relevant to carotid and vertebral artery interventions up to May 2010. The recommendations are evidence-based, derived from studies, reviews, and other evidence conducted in human subjects and published in English. The writing committee performed a formal literature review, weighed the strength of evidence for or against particular tests, treatments, or procedures, and included estimates of expected health outcomes where data exist.

Target Population: The target population includes patients with extracranial carotid and vertebral artery disease, both symptomatic and asymptomatic. The guideline addresses patient populations residing in North America and includes recommendations for primary care clinicians, medical and surgical cardiovascular specialists, trainees in primary care and vascular specialties, nurses, and other healthcare personnel.

Key Factors:

Anatomy and Definitions: The guideline provides detailed descriptions of the normal anatomy of the aortic arch and cervical arteries, variations in anatomy, and definitions related to extracranial cerebrovascular disease.

Epidemiology: It discusses the prevalence of stroke and extracranial cerebrovascular disease, including data from population studies and the impact of geographic variations.

Clinical Presentation: The guideline covers the natural history of atherosclerotic carotid artery disease, characterization of atherosclerotic lesions, symptoms and signs of transient ischemic attack (TIA) and ischemic stroke, and public awareness of stroke risk factors and warning indicators.

Diagnosis and Testing: Recommendations for diagnostic testing in patients with symptoms or signs of extracranial carotid artery disease, including the use of duplex ultrasonography, magnetic resonance angiography (MRA), computed tomographic angiography (CTA), and catheter-based contrast angiography.

Medical Therapy: Recommendations for the treatment of hypertension, cessation of tobacco smoking, control of hyperlipidemia, management of diabetes mellitus, and antithrombotic therapy in patients with extracranial carotid atherosclerotic disease.

Revascularization: Detailed recommendations for carotid endarterectomy (CEA) and carotid artery stenting (CAS), including factors affecting the outcome, risks associated with the procedures, and comparative assessments.

Special Populations: Recommendations for neurological risk reduction in patients with carotid artery disease undergoing cardiac or noncardiac surgery.

Nonatherosclerotic Carotid and Vertebral Artery Diseases: Management of fibromuscular dysplasia (FMD) and cervical artery dissection.

2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association⁽⁶⁾

Study Design: The study is a guideline from the American Heart Association/American Stroke Association, reviewed for evidence-based integrity and endorsed by several neurological and vascular societies. It is based on systematic methods to evaluate and classify evidence, aiming to provide recommendations for the prevention of stroke in patients with stroke and transient ischemic attack (TIA).

Target Population: The guidelines are applicable to patients with or at risk of developing cerebrovascular disease, focusing primarily on medical practice in the United States but relevant globally. The target population includes individuals who have experienced ischemic stroke or TIA, with specific recommendations tailored to various subtypes of stroke and risk factors.

Key Factors

Diagnostic Workup: Recommendations for diagnostic evaluation after ischemic stroke to define etiology and identify treatment targets to reduce recurrent stroke risk.

Vascular Risk Factor Management: Emphasis on managing vascular risk factors such as diabetes, smoking cessation, lipids, and hypertension through intensive medical management by multidisciplinary teams.

Lifestyle Factors: Importance of healthy diet and physical activity, with recommendations for low-salt and Mediterranean diets and supervised physical activity.

Antithrombotic Therapy: Recommendations for antithrombotic therapy, including antiplatelet or anticoagulant agents, with specific guidelines for dual antiplatelet therapy in certain high-risk patients.

Atrial Fibrillation: Management of atrial fibrillation with anticoagulation and heart rhythm monitoring.

Carotid and Intracranial Stenosis: Recommendations for intervention in patients with severe stenosis, including carotid endarterectomy and stenting.

Patent Foramen Ovale: Guidelines for percutaneous closure in patients with specific criteria.

Health Systems-Based Interventions: Importance of quality monitoring and improvement programs, multidisciplinary team-based approaches, and decision support tools for secondary stroke prevention.

Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease ⁽⁷⁾

Study Design: The guidelines are based on extensive investigations, including multiple randomized controlled trials (RCTs) and systematic reviews. The recommendations are made using the GRADE (grades of recommendation assessment, development, and evaluation) approach.

Target Population: The target population includes patients with carotid bifurcation stenosis, both symptomatic and asymptomatic. Specific emphasis is placed on low-risk surgical patients, patients presenting with acute stroke, and patients with combined carotid and coronary artery disease.

Key Factors

Carotid Endarterectomy (CEA) vs. Maximal Medical Therapy: CEA is recommended over maximal medical therapy for low-risk patients with asymptomatic carotid bifurcation atherosclerosis and stenosis of >70%. CEA is also recommended over transfemoral carotid artery stenting (TF-CAS) for low surgical risk patients with symptomatic carotid artery stenosis of >50%.

Timing of Carotid Intervention: Carotid revascularization is recommended for symptomatic patients with >50% stenosis to be performed as soon as the patient is neurologically stable after 48 hours but definitely before 14 days after symptom onset.

Screening for Carotid Artery Stenosis: Routine screening for clinically asymptomatic carotid artery stenosis in individuals without cerebrovascular symptoms or significant risk factors is not recommended. Screening is suggested for selected asymptomatic patients at increased risk of carotid stenosis, especially if they are willing to consider carotid intervention if significant stenosis is discovered.

Optimal Sequence of Intervention for Combined Carotid and Coronary Artery Disease: For patients with symptomatic carotid stenosis of 50% to 99% who require both CEA and coronary artery bypass grafting (CABG), CEA is suggested before or concomitant with CABG to potentially reduce the risk of stroke and stroke/death.

ANALYSIS OF EVIDENCE

Shared Conclusions

1. Carotid Endarterectomy (CEA) vs. Carotid Artery Stenting (CAS)

- All three articles emphasize the importance of CEA over CAS for patients with symptomatic carotid artery stenosis. AbuRahma et al. recommend CEA for low- and standard-risk patients with >50% symptomatic carotid artery stenosis. ⁽⁷⁾ Brott et al. also highlight the preference for CEA over CAS in symptomatic patients due to lower periprocedural stroke and death rates. ⁽⁸⁾ Kleindorfer et al. reiterate the importance of fixing severe stenosis in patients with symptomatic carotid artery disease. ⁽⁶⁾

2. Medical Management and Risk Factor Control

- The importance of aggressive medical management, including blood pressure control, lipid-lowering therapy, and lifestyle modifications, is a common theme. AbuRahma et al. discuss the role of medical management in stroke prevention. ⁽⁷⁾ Brott et al. emphasize the need for comprehensive risk factor management, including hypertension and hyperlipidemia. ⁽⁸⁾ Kleindorfer et al. also stress the importance of managing vascular risk factors, including hypertension, diabetes, and lifestyle changes. ⁽⁶⁾

3. Screening and Diagnosis

- All three articles agree on the importance of screening for carotid artery stenosis in high-risk patients. AbuRahma et al. recommend screening for asymptomatic carotid artery stenosis in selected high-risk patients. ⁽⁷⁾ Brott et al. suggest noninvasive imaging for patients with symptomatic anterior circulation cerebral infarction or TIA. ⁽⁸⁾ Kleindorfer et al. also recommend noninvasive cervical carotid imaging for patients with symptomatic carotid artery disease. ⁽⁶⁾

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> ● Added new bullet-point to the General Statement section ● Checked the Medicare Advantage box in the Applicable Lines of Business table ● Added a Summary of Evidence and Analysis of Evidence ● Updated references
March 2025	<ul style="list-style-type: none"> ● Modified the second, Level-1 bullet-point in the Indications from: "Stenting will be performed more than 14 days after the onset of symptoms and ANY of the following", to: "Stenting should be performed no more than 14 days after the onset of symptoms"

Date	Summary
	for ANY of the following”
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1171 Carotid Artery Stenting • Added general statement for share-decision making • Updated clinical indications, limitation, and background sections • Removed Special Note section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guideline 7267 for Carotid Duplex

Guideline Number: Evolent_CG_7267	<u>Applicable Codes</u>	
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STATEMENT

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- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Carotid Duplex.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR CAROTID DUPLEX

- Asymptomatic patients
 - With known carotid stenosis, 15–50% stenosis followed on an annual basis, and > 50% stenosis followed every six months ^(6,7)
 - With carotid bruit to detect hemodynamically significant carotid stenosis ^(6,8)
 - With clinical evidence of atherosclerosis and ≥ 50% carotid stenosis in previous diagnosis treated with therapeutic interventions as annual surveillance to assess disease's progression ⁽⁶⁾ (**AUC Score 7**) ⁽⁷⁾

- With symptomatic peripheral artery disease (PAD), coronary artery disease (CAD), or atherosclerotic aortic aneurysm, with or without carotid bruit to detect hemodynamically significant carotid stenosis ^(6,8)
- ≥ 55 years old with two or more of the following risk factors ^(6,8):
 - Hypertension, hyperlipidemia, tobacco smoking, amaurosis fugax, diabetes, renal failure, a family history in a first-degree relative of atherosclerosis manifested before 60 years old, or a family history of ischemic stroke
- With clinically occult cerebral infarction noted on brain imaging studies to detect significant carotid artery stenosis ⁽⁸⁾
- With Fibromuscular Dysplasia (FMD) of carotid artery as annual surveillance to detect changes in the extent or severity of disease ⁽⁶⁾
- Symptomatic patients
 - With focal neurological symptoms corresponding to the territory supplied by the left or right internal carotid artery ⁽⁶⁾
 - With nonspecific neurological symptoms when cerebral ischemia is a plausible cause ⁽⁶⁾
 - In symptomatic patients with atherosclerotic subclavian artery disease (transient ischemic attack (TIA)/stroke, coronary subclavian steal syndrome, ipsilateral hemodialysis access dysfunction, severe ischemia) ^(6,9)
 - With vasculitis involving the extra cranial carotid arteries ⁽⁷⁾
 - With pulsatile neck mass and no prior carotid duplex performed within the last 6 months ⁽⁷⁾
- Cardiac surgery
 - Before elective coronary artery bypass graft (CABG) surgery ⁽⁸⁾ in patients ≥ 65 years old and in those with left main coronary stenosis, known PAD, a history of cigarette smoking, a history of stroke or TIA, or carotid bruit ^(6,10) (**AUC Score 6**) ⁽⁷⁾
 - In patients undergoing or are candidates for carotid endarterectomy (CEA) or carotid artery stenting (CAS) for completion imaging to reduce the risk of peri-operative stroke ⁽¹⁰⁾
 - After revascularization at 1-month baseline, and every 6 months for 2 years, then annually to assess patency and exclude the development of new or contralateral lesion ⁽⁶⁾

Note: Duplex ultrasonography may overestimate the severity of stenosis contralateral to internal carotid occlusion, suggesting the need for further confirmation with another imaging modality, especially in asymptomatic patients who are candidates for carotid revascularization ⁽⁶⁾

CODING AND STANDARDS

Codes

93880, 93882

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Non-invasive extra cranial arterial studies involve the use of direct methods of ultrasound. Duplex ultrasound is the first-line imaging modality for carotid artery imaging, screening, and examination the anatomy and physiology of the carotid artery. ⁽⁸⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: Coronary artery bypass graft

CAD: Coronary artery disease

CAS: Carotid artery stenting

FMD: Fibromuscular dysplasia

PAD: Peripheral artery disease

TIA: Transient ischemic attack

SUMMARY OF EVIDENCE

2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease ⁽⁶⁾

Study Design: The guideline is based on a thorough review of the literature relevant to carotid and vertebral artery interventions up to May 2010. The recommendations are evidence-based, derived from studies, reviews, and other evidence conducted in human subjects and published in English. The writing committee performed a formal literature review, weighed the strength of evidence for or against particular tests, treatments, or procedures, and included estimates of expected health outcomes where data exist.

Target Population: The target population includes patients with extracranial carotid and vertebral artery disease, both symptomatic and asymptomatic. The guideline addresses patient populations residing in North America and includes recommendations for primary care clinicians, medical and surgical cardiovascular specialists, trainees in primary care and vascular specialties, nurses, and other healthcare personnel.

Key Factors:

Anatomy and Definitions: The guideline provides detailed descriptions of the normal anatomy of the aortic arch and cervical arteries, variations in anatomy, and definitions related to extracranial cerebrovascular disease.

Epidemiology: It discusses the prevalence of stroke and extracranial cerebrovascular disease, including data from population studies and the impact of geographic variations.

Clinical Presentation: The guideline covers the natural history of atherosclerotic carotid artery disease, characterization of atherosclerotic lesions, symptoms and signs of transient ischemic attack (TIA) and ischemic stroke, and public awareness of stroke risk factors and warning indicators.

Diagnosis and Testing: Recommendations for diagnostic testing in patients with symptoms or signs of extracranial carotid artery disease, including the use of duplex ultrasonography, magnetic resonance angiography (MRA), computed tomographic angiography (CTA), and catheter-based contrast angiography.

Medical Therapy: Recommendations for the treatment of hypertension, cessation of tobacco smoking, control of hyperlipidemia, management of diabetes mellitus, and antithrombotic therapy in patients with extracranial carotid atherosclerotic disease.

Revascularization: Detailed recommendations for carotid endarterectomy (CEA) and carotid artery stenting (CAS), including factors affecting the outcome, risks associated with the procedures, and comparative assessments.

Special Populations: Recommendations for neurological risk reduction in patients with carotid artery disease undergoing cardiac or noncardiac surgery.

Nonatherosclerotic Carotid and Vertebral Artery Diseases: Management of fibromuscular dysplasia (FMD) and cervical artery dissection.

ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part I: Arterial Ultrasound and Physiological Testing ⁽⁷⁾

Study Design: This document is the 2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing, Part I: Arterial Ultrasound and Physiological Testing. It was developed by the American College of Cardiology Foundation Appropriate Use Criteria Task Force in partnership with several other societies.

Target Population: The criteria are intended for patients undergoing peripheral vascular ultrasound and physiological testing for various arterial disorders, including cerebrovascular disease, renal artery stenosis, mesenteric artery stenosis, abdominal aortic disease, and lower and upper extremity arterial disease.

Key Factors: The document provides detailed criteria for the appropriate use of peripheral vascular ultrasound and physiological testing based on various clinical scenarios. It includes indications for testing, surveillance after revascularization, and follow-up care. The criteria are intended to guide clinicians in maximizing the appropriate use of noninvasive vascular laboratory testing for the care of patients with peripheral vascular disorders.

Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease ⁽⁸⁾

Study Design: The guidelines are based on extensive investigations, including multiple randomized controlled trials (RCTs) and systematic reviews. The recommendations are made using the GRADE (grades of recommendation assessment, development, and evaluation) approach.

Target Population: The target population includes patients with carotid bifurcation stenosis, both symptomatic and asymptomatic. Specific emphasis is placed on low-risk surgical patients, patients presenting with acute stroke, and patients with combined carotid and coronary artery disease.

Key Factors

Carotid Endarterectomy (CEA) vs. Maximal Medical Therapy: CEA is recommended over maximal medical therapy for low-risk patients with asymptomatic carotid bifurcation atherosclerosis and stenosis of >70%. CEA is also recommended over transfemoral carotid artery stenting (TF-CAS) for low surgical risk patients with symptomatic carotid artery stenosis of >50%.

Timing of Carotid Intervention: Carotid revascularization is recommended for symptomatic patients with >50% stenosis to be performed as soon as the patient is neurologically stable after 48 hours but definitely before 14 days after symptom onset.

Screening for Carotid Artery Stenosis: Routine screening for clinically asymptomatic carotid artery stenosis in individuals without cerebrovascular symptoms or significant risk factors is not recommended. Screening is suggested for selected asymptomatic patients at increased risk of carotid stenosis, especially if they are willing to consider carotid intervention if significant stenosis is discovered.

Optimal Sequence of Intervention for Combined Carotid and Coronary Artery Disease: For patients with symptomatic carotid stenosis of 50% to 99% who require

both CEA and coronary artery bypass grafting (CABG), CEA is suggested before or concomitant with CABG to potentially reduce the risk of stroke and stroke/death.

ANALYSIS OF EVIDENCE

Shared Findings ^(6–8)

Importance of Carotid Endarterectomy (CEA) and Carotid Artery Stenting (CAS):

All three articles emphasize the significance of CEA and CAS in managing carotid artery disease. They agree that these procedures are crucial for preventing stroke in patients with significant carotid stenosis.

Role of Medical Therapy: The articles highlight the role of medical therapy in managing carotid artery disease. They agree that medical therapy, including antiplatelet agents, statins, and antihypertensive medications, is essential for all patients, regardless of whether they undergo CEA or CAS.

Screening and Surveillance: The importance of screening and surveillance for carotid artery disease is a common theme. The articles agree that regular follow-up and imaging are necessary to monitor disease progression and the effectiveness of interventions.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none"> Updated indication for asymptomatic patients with known carotid stenosis from 30-50% followed on an annual basis to 15-50% followed on an annual basis
June 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> Added new bullet-point to the General Statement section Checked the Medicare Advantage box in the Applicable Lines of Business table No clinical changes
December 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1081 Carotid Duplex Updated indications for Carotid Duplex Updated references Removed Special Note and Limitation sections

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evotent Clinical Guideline 7268 for Carotid Endarterectomy

Guideline Number: Evotent_CG_7268	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Carotid Endarterectomy. Carotid endarterectomy (CEA) is a surgical procedure used to prevent stroke, by correcting stenosis (narrowing) in the common or internal carotid artery. Endarterectomy is the removal of material on the inside of an artery.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS

Symptomatic Patients

- Patients with $\geq 50\%$ stenosis, and low to standard surgical risk (when a patient doesn't have high-risk medical or surgical factors) ^(6,7)
 - For patients with high grade carotid artery stenosis, intervention is most successful

within 2 weeks of symptom onset ⁽⁷⁾

- Patients with history of stroke
 - For neurologically stable patients with recent stable stroke or transient ischemic attack (TIA) and >50% stenosis between 48 hours and 14 days after symptom onset ⁽⁶⁻⁸⁾
 - In patients with 70-99% stenosis and nondisabling TIA or stroke within the past 6 months ⁽⁸⁾
 - In patients 70 years or older with stroke or TIA, CEA is appropriate instead of carotid artery stenosis (CAS) to reduce periprocedural stroke rate ⁽⁸⁾
 - In patients with carotid web and history of stroke ⁽⁸⁾

Asymptomatic Patients

- For patients at high risk of stroke in conjunction with medical therapy, when the perioperative risk is less than 3% ⁽⁷⁾
- For patients with > 70% stenosis and low surgical risk in conjunction with best medical therapy ⁽⁶⁾

NOTE: Selection of asymptomatic patients for carotid revascularization should be guided by an assessment of comorbid conditions, life expectancy, and other individual factors and should include a thorough discussion of the risk and benefits of the procedure with an understanding of patient's preferences.

CODING AND STANDARDS

Codes

35301

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CAS: Carotid Artery Stenosis

CEA: Carotid Endarterectomy

TIA: Transient Ischemic Attack

SUMMARY OF EVIDENCE

Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease ⁽⁶⁾

Study Design: The guidelines are based on extensive investigations, including multiple randomized controlled trials (RCTs) and systematic reviews. The recommendations are made using the GRADE (grades of recommendation assessment, development, and evaluation) approach.

Target Population: The target population includes patients with carotid bifurcation stenosis, both symptomatic and asymptomatic. Specific emphasis is placed on low-risk surgical patients, patients presenting with acute stroke, and patients with combined carotid and coronary artery disease.

Key Factors

Carotid Endarterectomy (CEA) vs. Maximal Medical Therapy: CEA is recommended over maximal medical therapy for low-risk patients with asymptomatic carotid bifurcation atherosclerosis and stenosis of >70%. CEA is also recommended over transfemoral carotid artery stenting (TF-CAS) for low surgical risk patients with symptomatic carotid artery stenosis of >50%.

Timing of Carotid Intervention: Carotid revascularization is recommended for symptomatic patients with >50% stenosis to be performed as soon as the patient is neurologically stable after 48 hours but definitely before 14 days after symptom onset.

Screening for Carotid Artery Stenosis: Routine screening for clinically asymptomatic carotid artery stenosis in individuals without cerebrovascular symptoms or significant risk factors is not recommended. Screening is suggested for selected asymptomatic patients

at increased risk of carotid stenosis, especially if they are willing to consider carotid intervention if significant stenosis is discovered.

Optimal Sequence of Intervention for Combined Carotid and Coronary Artery Disease: For patients with symptomatic carotid stenosis of 50% to 99% who require both CEA and coronary artery bypass grafting (CABG), CEA is suggested before or concomitant with CABG to potentially reduce the risk of stroke and stroke/death.

Medical and Surgical Management of Symptomatic and Asymptomatic Carotid Artery Stenosis: A Comprehensive Literature Review ⁽⁷⁾

Study Design: The study is a literature review that examines various aspects of carotid artery stenosis, including its pathophysiology, risk factors, importance of early detection and treatment, and the surgical approaches of carotid endarterectomy (CEA) and carotid artery stenting (CAS).

Target Population: The target population includes elderly individuals with high cardiovascular risk, smokers, those with high cholesterol, males, and older individuals. Young females may also be affected by fibromuscular dysplasia.

Key Factors

Carotid Artery Stenosis: A condition where the carotid artery is blocked by fatty cholesterol deposits called plaque, increasing the risk of stroke.

Risk Factors: Smoking, hyperlipidemia, male gender, age, and fibromuscular dysplasia in young females.

Treatment Options: Medical and surgical interventions, such as carotid endarterectomy (CEA) and carotid artery stenting (CAS).

Importance of Early Detection: Early detection and treatment are essential to prevent complications.

Surgical Approaches: The review explores the roles and controversies of CEA and CAS in managing carotid artery stenosis.

2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association ⁽⁸⁾

Study Design: The study is a guideline from the American Heart Association/American Stroke Association, reviewed for evidence-based integrity and endorsed by several neurological and vascular societies. It is based on systematic methods to evaluate and classify evidence, aiming to provide recommendations for the prevention of stroke in patients with stroke and transient ischemic attack (TIA).

Target Population: The guidelines are applicable to patients with or at risk of developing cerebrovascular disease, focusing primarily on medical practice in the United States but relevant globally. The target population includes individuals who have experienced ischemic stroke or TIA, with specific recommendations tailored to various subtypes of stroke and risk factors.

Key Factors

Diagnostic Workup: Recommendations for diagnostic evaluation after ischemic stroke to define etiology and identify treatment targets to reduce recurrent stroke risk.

Vascular Risk Factor Management: Emphasis on managing vascular risk factors such as diabetes, smoking cessation, lipids, and hypertension through intensive medical management by multidisciplinary teams.

Lifestyle Factors: Importance of healthy diet and physical activity, with recommendations for low-salt and Mediterranean diets and supervised physical activity.

Antithrombotic Therapy: Recommendations for antithrombotic therapy, including antiplatelet or anticoagulant agents, with specific guidelines for dual antiplatelet therapy in certain high-risk patients.

Atrial Fibrillation: Management of atrial fibrillation with anticoagulation and heart rhythm monitoring.

Carotid and Intracranial Stenosis: Recommendations for intervention in patients with severe stenosis, including carotid endarterectomy and stenting.

Patent Foramen Ovale: Guidelines for percutaneous closure in patients with specific criteria.

Health Systems-Based Interventions: Importance of quality monitoring and improvement programs, multidisciplinary team-based approaches, and decision support tools for secondary stroke prevention.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(6–8)

1. **Importance of Early Detection and Treatment:** All three articles emphasize the significance of early detection and treatment of carotid artery stenosis to prevent stroke and other cardiovascular events. They agree that timely intervention can significantly reduce the risk of recurrent strokes and improve patient outcomes.
2. **Surgical and Medical Management:** The articles discuss both surgical and medical management options for carotid artery stenosis. Carotid endarterectomy (CEA) and carotid artery stenting (CAS) are highlighted as effective surgical interventions. Medical management, including antiplatelet therapy, statins, and lifestyle modifications, is also emphasized as crucial for preventing recurrent strokes.
3. **Risk Factors and Patient Selection:** The articles agree on the importance of considering patient-specific risk factors and characteristics when deciding on the treatment approach. Factors such as age, comorbidities, and the severity of stenosis are critical in determining whether a patient should undergo surgical or medical management.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> Added new bullet-point to the General Statement section Checked the Medicare Advantage box in the Applicable Lines of Business table No clinical changes
January 2025	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1163 for Carotid Endarterectomy Updated references Reorganized and clarified indications

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established,



we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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1. Patel MR, Spertus JA, Brindis RG, et al. ACCF Proposed Method for Evaluating the Appropriateness of Cardiovascular Imaging. *J Am Coll Cardiol*. 2005;46(8):1606-1613. doi:10.1016/j.jacc.2005.08.030
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3. Hendel RC, Patel MR, Allen JM, et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF appropriate use criteria methodology update. *J Am Coll Cardiol*. 2013;61(12):1305-1317. doi:10.1016/j.jacc.2013.01.025
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Evolent Clinical Guideline 7269 for Catheter Based Carotid and Brachiocephalic Arteriography, Venography, and Intervention

Guideline Number: Evolent_CG_7269	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: July 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Catheter Based Carotid and Brachiocephalic Arteriography, Venography, and Intervention.

Note: Indications related to evaluation of the brain, cerebral perfusion and anatomy are not included in this guideline

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS FOR CATHETER BASED CAROTID ARTERY DIGITAL ANGIOGRAPHY ⁽⁶⁾

- When there are conflicting or inconclusive results from prior duplex scan, computed tomography angiography (CTA) and/or magnetic resonance angiography (MRA) and carotid revascularization is being contemplated

- When there is/are contraindications to CTA/MRA and carotid artery revascularization is being contemplated
- In patients with renal dysfunction to limit exposure to contrast material during evaluation of a single vascular territory
- For the diagnosis of cervical artery dissection
- For the evaluation of carotid fibromuscular dysplasia
- For the evaluation of vertebral artery dissection and obstructive lesions
- For the evaluation of cervical or cranial aneurysms
- For the evaluation of cervical or cranial malignancies

INDICATIONS FOR HEMODIALYSIS-RELATED ISSUES

Hemodialysis related complications can occur outside the dialysis circuit, necessitating further visualization and treatment.

- Catheter directed arteriography and/or angioplasty/stent may be performed when **ALL** of the following conditions are met:
 - **The catheter is inserted in one of the following manners** ^(7,8):
 - Through a puncture at a different site than the dialysis circuit
 - Via the dialysis circuit and positioned in the aorta or subclavian artery
 - **Arteriography is employed to examine/treat possible pathologies when at least ONE of the following applies** ^(7,8):
 - Steal syndrome or distal limb ischemia is suspected
 - A fistulogram has been performed for hemodialysis issues, and no pathology or reason for decreased flow was visualized
- Venography may be performed when the catheter is inserted from a vein outside the dialysis circuit for a tunneled catheter replacement
- Venous angioplasty/stents can be performed on veins that are not part of the dialysis circuit but have caused complications due to stenosis or occlusion when at least ONE of the following applies:
 - The stenosis involves a vein distal to, and not involving, the distal anastomosis of a dialysis access graft
 - The stenosis involves a vein distal to, and not involving, the cephalic arch (which is the junction of the cephalic vein and axillary vein)
 - A fibrous sheath has caused occlusion or loss of function of a tunneled dialysis

catheter

LIMITATIONS FOR CATHETER BASED CAROTID ARTERY DIGITAL ANGIOGRAPHY

- Catheter-based angiography is unnecessary for diagnostic evaluation of most patients with Extracranial Carotid and Vertebral Artery Disease (ECVD), especially preoperatively before carotid endarterectomy (CEA) ⁽⁹⁾ and is used increasingly as a therapeutic revascularization maneuver in conjunction with stent deployment ⁽⁶⁾

CODING AND STANDARDS

Codes

36215, 36216, 36217, 36218, 36221, 36222, 36223, 36224, 36225, 36226, 36227, 36228, 37236, 37237, 37238, 37239, 37246, 37247, 37248, 37249, 75710

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Carotid angiography is a procedure performed in order to visualize the arterial supply to the brain and to ascertain presence of blockage in the extra cranial carotid arteries.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CEA: Carotid endarterectomy

CTA: Computed tomography angiography

ECVD: Extracranial Carotid and Vertebral Artery Disease

MRA: Magnetic resonance angiography

SUMMARY OF EVIDENCE

2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease ⁽⁶⁾

Study Design: The guideline is based on a thorough review of the literature relevant to carotid and vertebral artery interventions up to May 2010. The recommendations are evidence-based, derived from studies, reviews, and other evidence conducted in human subjects and published in English. The writing committee performed a formal literature review, weighed the strength of evidence for or against particular tests, treatments, or procedures, and included estimates of expected health outcomes where data exist.

Target Population: The target population includes patients with extracranial carotid and vertebral artery disease, both symptomatic and asymptomatic. The guideline addresses patient populations residing in North America and includes recommendations for primary care clinicians, medical and surgical cardiovascular specialists, trainees in primary care and vascular specialties, nurses, and other healthcare personnel.

Key Factors:

Anatomy and Definitions: The guideline provides detailed descriptions of the normal anatomy of the aortic arch and cervical arteries, variations in anatomy, and definitions related to extracranial cerebrovascular disease.

Epidemiology: It discusses the prevalence of stroke and extracranial cerebrovascular disease, including data from population studies and the impact of geographic variations.

Clinical Presentation: The guideline covers the natural history of atherosclerotic carotid artery disease, characterization of atherosclerotic lesions, symptoms and signs of transient ischemic attack (TIA) and ischemic stroke, and public awareness of stroke risk factors and warning indicators.

Diagnosis and Testing: Recommendations for diagnostic testing in patients with symptoms or signs of extracranial carotid artery disease, including the use of duplex

ultrasonography, magnetic resonance angiography (MRA), computed tomographic angiography (CTA), and catheter-based contrast angiography.

Medical Therapy: Recommendations for the treatment of hypertension, cessation of tobacco smoking, control of hyperlipidemia, management of diabetes mellitus, and antithrombotic therapy in patients with extracranial carotid atherosclerotic disease.

Revascularization: Detailed recommendations for carotid endarterectomy (CEA) and carotid artery stenting (CAS), including factors affecting the outcome, risks associated with the procedures, and comparative assessments.

Special Populations: Recommendations for neurological risk reduction in patients with carotid artery disease undergoing cardiac or noncardiac surgery.

Nonatherosclerotic Carotid and Vertebral Artery Diseases: Management of fibromuscular dysplasia (FMD) and cervical artery dissection.

Upper Extremity Catheter Angiography: Indications, Techniques, Anatomy, and Classic Cases ⁽⁷⁾

Study Design: The study design is a pictorial essay that discusses the indications, techniques, anatomy, and classic cases of upper extremity catheter angiography. The target population includes patients with various pathophysiologic conditions such as trauma, limb ischemia, hemodialysis access, vasculitis, and vascular anomalies. The study reviews modern indications of upper extremity catheter angiography, patient preparation, angiographic techniques, normal and variant anatomy, and classic angiographic diagnoses.

Key factors:

Indications: Trauma, acute limb ischemia, bypass graft planning, dialysis access steal syndrome, vasculitis, and vascular anomalies.

Techniques: Preparation and patient positioning, equipment and access, vasodilators.

Diagnosis: Anatomy and variants, classic angiographic cases such as Takayasu's arteritis, arterial thoracic outlet syndrome, thromboangiitis obliterans (Buerger's disease), hypothenar hammer syndrome, and Raynaud's phenomenon.

The study emphasizes the importance of catheter angiography in specific clinical scenarios despite advancements in computed tomography/magnetic resonance angiography (CT/MRA).

New bundled CPT codes for dialysis circuit interventions ⁽⁸⁾

Study Design: The study was conducted by a joint workgroup of the American Medical Association Current Procedural Terminology (CPT) and Specialty Society Relative Value Scale Update Committee (RUC). The workgroup identified a number of CPT codes that were billed together 75% or more of the time and proposed a code change to bundle these codes. The proposal was reviewed at the October 2015 CPT Editorial Panel meeting, and the new codes and coding guidelines became effective on January 1, 2017.

Target Population: The target population for this study includes patients undergoing dialysis circuit interventions. The study focuses on the percutaneous management of dialysis access circuits, including angioplasty, thrombectomy, and stent placement procedures.

Key Factors

New Codes: The study introduced nine new bundled codes to describe dialysis circuit intervention services. These codes are hierarchical and describe increasing intensity of intervention.

Peripheral and Central Segments: The hemodialysis circuit is divided into peripheral and central segments. The peripheral segment includes the arterial anastomosis and extends to the central segment, while the central segment includes the subclavian and innominate veins through the superior vena cava.

Diagnostic and Therapeutic Procedures: The new codes cover various diagnostic and therapeutic procedures, including needle and catheter placement, angioplasty, stent placement, thrombectomy, and embolization.

Coding Guidelines: The study provides detailed coding guidelines for reporting these procedures, including the bundling of certain services and the appropriate use of add-on codes.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(6–8)

1. **Importance of Imaging Techniques:** All three articles emphasize the critical role of imaging techniques in diagnosing and managing vascular conditions. Roddy and Lerner discuss the use of imaging for dialysis circuit interventions, Brott et al highlight noninvasive imaging for carotid and vertebral artery disease, and Shin et al focus on catheter angiography for upper extremity conditions.
2. **Need for Comprehensive Guidelines:** Both Roddy and Lerner and Brott et al stress the importance of having detailed guidelines to standardize procedures and improve patient outcomes. Roddy and Lerner provide coding guidelines for dialysis interventions, while Brott et al offer recommendations for managing carotid and vertebral artery disease.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none"> Guideline name was changed from ECG 7269 for Catheter Based Carotid and Brachiocephalic Artery Digital Angiography to ECG 7269 for Catheter Based Carotid and Brachiocephalic Arteriography, Venography, and Intervention Added section on venous angioplasty

Date	Summary
	<ul style="list-style-type: none"> Added CPT codes 37236, 37237, 37238, 37239, 37246, 37247, 37248, 37249, and 75710
June 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> Added new bullet-point to the General Statement section No clinical changes
January 2025	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1169 Catheter Based Carotid Artery Digital Angio Updated according to societal guidelines Added missing CPT code 36228 Added hemodialysis-related indication section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established,



we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7270 for Central Venous Access Procedure

Guideline Number: Evolent_CG_7270	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: May 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Central Venous Access Device (CVAD) implantation and removal.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS FOR CVAD IMPLANTATION ^(6,7)

Indications	Usually Appropriate	May Be Appropriate	Usually Not Appropriate
Administration of IV medication (> 2 weeks) (excluding chemotherapy)	PICC, Tunneled CVC	Chest port, Arm port	Non-tunneled CVC

Indications	Usually Appropriate	May Be Appropriate	Usually Not Appropriate
Administration of IV medication that may irritate peripheral endothelium	Non-tunneled CVC, PICC	Tunneled CVC, Midline catheter	Arm port, Chest port
Frequent blood sampling	Non-tunneled CVC, PICC	Tunneled CVC, Midline catheter	Arm port, Chest port
Hemodialysis prior to AVF creation	Non-tunneled CVC (≤ 2 weeks), Tunneled CVC	Non-tunneled CVC (> 2 weeks)	Arm port, Chest port, PICC
Hemodynamic monitoring	Non-tunneled CVC, PICC	Tunneled CVC, Midline catheter	Arm port, Chest port
Administration of chemotherapy (> 2 weeks)	Chest port, Arm port	PICC, Tunneled CVC	Non-tunneled CVC

INDICATIONS FOR CVAD REMOVAL

- If the central venous access is no longer clinically needed
- Catheter occlusion
- Central venous thrombosis
- Fibrin sheath formation
- Catheter-related infection
- Catheter kinking

CODING AND STANDARDS

Codes

- CVAD Insertion: 36556, 36558, 36561, 36563, 36565, 36566
- CVAD Removal: 32552, 36589, 36590
- CVAD Replacement: 36578, 36580, 36581, 36582, 36583
- CVAD Repair: 36575, 36576,
- Fluoroscopic Guidance/Contrast: 36597, 36598, 76000, 77001

Place of Services Codes

Inpatient hospital (21)

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Central Venous Access Device: a catheter that is placed in a vein that leads directly to the right side of the heart. There are a number of central veins and for each of these there are a variety of techniques. Catheters are available which differ in length, internal diameter, number of channels, method of insertion, material and means of fixation.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AVF: Arteriovenous fistula

CVAD: Central venous access device

CVC: Central venous catheter

IV: Intravenous

PICC: Peripherally inserted central catheter

SUMMARY OF EVIDENCE (6)

Study Design: The document is a systematic review and guideline developed by an expert panel on interventional radiology. It evaluates the literature supporting the selection of central venous access devices and the site of placement in various clinical settings. The review includes data from multiple studies, including randomized controlled trials, prospective cohort studies, and systematic reviews.

Target Population: The target population includes patients requiring central venous access for various medical conditions such as acute illness, renal failure, cancer, and the need for long-term intravenous medication or parenteral nutrition. Specific patient groups addressed include those with acute renal failure, chronic kidney disease, cancer, and those requiring frequent intravenous administration of medications.

Key Factors:

Device Selection: The document provides recommendations for different types of central venous access devices, including nontunneled central venous catheters (CVCs), peripherally inserted central catheters (PICCs), tunneled dialysis catheters, and central venous ports (chest and arm ports). The appropriateness of each device is categorized based on the clinical scenario, such as the duration of therapy, the type of medication administered, and the patient's underlying condition.

Site Selection: Recommendations are provided for the optimal site of catheter insertion, including the internal jugular vein, subclavian vein, external jugular vein, femoral vein, hepatic vein, and inferior vena cava. The appropriateness of each site is evaluated based on factors such as the risk of infection, mechanical complications, and the patient's clinical condition.

Clinical Scenarios: The document outlines specific clinical scenarios and provides evidence-based recommendations for device and site selection. For example, it addresses scenarios such as acutely ill patients requiring short-term therapy, patients with renal failure needing long-term dialysis, and cancer patients requiring chemotherapy.

Literature Review: The document includes a summary of the literature review, highlighting key studies and their findings. It discusses the benefits and risks associated with different types of central venous access devices and insertion sites.

Expert Panel: The guidelines were developed by an expert panel consisting of radiologists, interventional radiologists, and other specialists. The panel reviewed the available evidence and provided consensus recommendations.

ANALYSIS OF EVIDENCE (6)

The guideline provides recommendations for selecting central venous access devices and sites based on various clinical scenarios. For acutely ill patients, nontunneled central venous catheters (CVC) and peripherally inserted central catheters (PICC) are usually appropriate for short-term use. For patients with acute renal failure, nontunneled and tunneled dialysis catheters are suitable for short-term renal replacement therapy, while tunneled dialysis catheters are recommended for long-term therapy in patients with renal failure. Cancer patients

requiring chemotherapy infusions are advised to use chest and arm ports, and for continuous IV medication administration, PICC and tunneled CVC are suitable for long-term use. For long-term total parenteral nutrition, double lumen tunneled CVC and double lumen PICC are recommended, and single or double lumen tunneled CVC are appropriate for chronic kidney disease patients requiring long-term IV infusions. Site selection for acutely ill patients generally includes internal jugular, subclavian, and upper extremity veins, while internal jugular veins are usually appropriate for chronic kidney disease patients.

The document also emphasizes the importance of selecting the appropriate device and site to minimize complications and improve patient outcomes. It highlights the benefits and risks associated with different types of central venous access devices and sites, stressing the need for careful consideration based on the patient's clinical condition. The guidelines aim to provide a comprehensive approach to central venous access device and site selection, ensuring optimal care and minimizing potential complications.

POLICY HISTORY

Date	Summary
May 2025	<ul style="list-style-type: none"> Added new bullet-point to the General Statement section Added a Summary of Evidence and Analysis of Evidence
November 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1166 Central Venous Access Procedures

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7271 for Coronary Fractional Flow Reserve

Guideline Number: Evolent_CG_7271	<u>Applicable Codes</u>	
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Original Date: May 2016	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Coronary Fractional Flow Reserve

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR CORONARY FRACTIONAL FLOW RESERVE ⁽⁶⁾

- In patients with angina or an anginal equivalent, undocumented ischemia, and angiographically intermediate stenoses (defined as a diameter stenosis severity of 40% to 69%) to guide the decision to proceed with PCI (percutaneous coronary intervention)
- In patients undergoing valve surgery, aortic surgery, or other cardiac operations with intermediate coronary artery disease (CAD; defined as 40%–69% stenosis) to guide the decision to proceed with or without concomitant CABG (coronary artery bypass graft)

CODING AND STANDARDS

Codes

93571, 93572

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Fractional flow reserve (FFR) is used to determine the functional significance of a coronary stenosis in angiographically "intermediate" or "indeterminant" lesions which allows the operator to decide when PCI may be beneficial or safely deferred. During coronary catheterization, a catheter is inserted into the femoral (groin) or radial arteries (wrist) using a sheath and guidewire. FFR is calculated as the ratio of distal coronary pressure to aortic pressure measured during maximal hyperemia. A normal value for FFR is 1.0. FFR \leq 0.80 in an angiographically intermediate lesion (50-70% stenosis) is considered to be a significant coronary lesion (>70% stenosis). ⁽⁷⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: Coronary artery bypass graft

CAD: Coronary artery disease

FFR: Fractional flow reserve

PCI: Percutaneous coronary intervention

SUMMARY OF EVIDENCE

2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization ⁽⁶⁾

Study Design: The guidelines are based on a comprehensive literature search conducted from May 2019 to September 2019, which included studies, reviews, and other evidence conducted on human subjects and published in English. The search covered databases such as PubMed, EMBASE, the Cochrane Collaboration, and CINHL Complete. Additional relevant studies published through May 2021 were also considered.

Target Population: The target population includes patients with coronary artery disease (CAD) who are being considered for coronary revascularization. This includes patients with stable ischemic heart disease (SIHD), acute coronary syndromes (ACS), and those undergoing percutaneous coronary intervention (PCI).

Key Factors:

FFR and iFR Use: FFR and instantaneous wave-free ratio (iFR) are physiological methods used to assess lesion significance in patients with angina or angina equivalent and angiographically intermediate stenoses. FFR is defined as the ratio of maximal blood flow in a region distal to a lesion compared with the normal maximal blood flow of an artery. iFR is an index of lesion severity measured during the wave-free period in diastole.

Clinical Trials and Outcomes: The FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) trial demonstrated that FFR-guided PCI reduced the risk of the composite endpoint of death, myocardial infarction (MI), or urgent revascularization compared with angiography-guided PCI. The DEFINE-FLAIR (Functional Lesion Assessment of Intermediate Stenosis to Guide Revascularization) and iFR-SWEDEHEART (Instantaneous Wave-Free Ratio versus Fractional Flow Reserve in Patients with Stable Angina Pectoris or Acute Coronary Syndrome) trials showed that iFR-guided PCI was noninferior to FFR-guided PCI in terms of clinical outcomes.

Recommendations: FFR or iFR is recommended to guide the decision to proceed with PCI in patients with angiographically intermediate stenoses and undocumented ischemia. PCI should not be performed in stable patients with angiographically intermediate stenoses and FFR >0.80 or iFR >0.89.

Safety and Efficacy: Deferral of PCI when FFR is >0.80 or iFR is >0.89 is associated with low rates of long-term major adverse cardiovascular events (MACE). The use of FFR and iFR has been shown to improve clinical outcomes by reducing unnecessary revascularizations and focusing treatment on lesions that are physiologically significant.

Fractional Flow Reserve Assessment of Coronary Artery Stenosis ⁽⁷⁾

Study Design: The document is a review article that discusses various aspects of CAD, including prevention, diagnosis, and treatment. It synthesizes findings from multiple studies and clinical trials to provide a thorough overview of the current state of knowledge in the field.

Target Population: The primary focus is on patients with coronary artery disease, particularly those with stable ischemic heart disease or acute coronary syndrome (ACS). The review addresses different patient subsets, including those with high-risk clinical conditions, moderate coronary lesions, and multivessel disease.

Key Factors:

Prevention: Emphasizes the importance of a healthy lifestyle, including diet, exercise, maintaining optimal body weight, and avoiding smoking, as the best method for preventing CAD.

Diagnosis: Discusses the use of coronary angiography and fractional flow reserve (FFR) to identify significant coronary lesions and assess their physiological impact. FFR is highlighted as the gold standard for detecting myocardial ischemia.

Treatment: Reviews the indications for revascularization, including percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG). It also covers the use of FFR to guide revascularization decisions in patients with stable CAD and intermediate coronary lesions.

Recent Advances: Mentions recent advances in non-invasive assessment techniques, such as computed tomographic angiography (CTA) and FFR-CT, which allow for the evaluation of coronary artery disease without invasive procedures.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(6,7)

Both articles focus on coronary artery disease (CAD) and the importance of revascularization in managing this condition. They emphasize the significance of identifying and treating significant coronary stenoses to improve patient outcomes.

1. **Revascularization Techniques:** Both articles discuss the use of percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) as primary revascularization techniques. They highlight the benefits of these procedures in reducing mortality and improving symptoms in patients with CAD.
2. **Fractional Flow Reserve (FFR):** Both articles mention the use of FFR as a critical tool in assessing the physiological significance of coronary stenoses. FFR helps determine whether revascularization is necessary based on the severity of blood flow impairment.
3. **Patient Selection:** Both articles stress the importance of patient selection for revascularization procedures. They recommend using clinical criteria, imaging, and physiological assessments to identify patients who would benefit the most from revascularization.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> Added new bullet-point to the General Statement section Added a Summary of Evidence and Analysis of Evidence
December 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1269 Coronary Fractional Flow Reserve Updated indications for Coronary Fractional Flow Reserve Updated Background and references Removed Special Note section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7274 for Coronary Intra Vascular Arterial Ultrasound

Guideline Number: Evolut_CG_7274	<u>Applicable Codes</u>	
<i>"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc.</i> <i>© 2016 - 2026 Evolent. All rights Reserved.</i>		
Original Date: May 2016	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Coronary Intra Vascular Arterial Ultrasound (IVUS).

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS

IVUS is recommended for:

- Assessing angiographically indeterminate left main (LM) artery lesion severity prior to revascularization ⁽⁶⁾
- Post cardiac transplantation within 4 to 6 weeks and 1 year to exclude donor coronary artery disease (CAD), detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information ⁽⁶⁾

- Evaluating the mechanism of stent failure, stent restenosis and stent thrombosis ^(6–8)
- Assessing non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis) ⁽⁶⁾
- Coronary stent implantation guidance, particularly in cases of LM coronary artery stenting or complex coronary artery stenting including but not limited to ^(6–9):
 - Adequate expansion and apposition in selected patients
- Assessing plaque extent (burden) and characteristics within the LM artery, ⁽⁹⁾ particularly ostial stenosis in LM artery and daughter branches ^(8,9)
- Assessing the severity and optimizing the treatment of unprotected LM artery lesions ⁽⁸⁾

Limitations

IVUS is **NOT** indicated for:

- Routine lesion assessment when revascularization with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) is not being contemplated ⁽⁶⁾
- Extreme vessel tortuosity and angulation ⁽¹⁰⁾
- Patients not suitable for systemic anticoagulation or angiography or cardiac catheterization ⁽¹⁰⁾

CODING AND STANDARDS

Codes

92978, 92979

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

IVUS is a specially designed catheter with a miniaturized ultrasound probe attached to the distal end of the catheter. IVUS when introduced in a coronary artery during cardiac catheterization, provides more precise information about the severity of stenosis and plaque morphology than does coronary angiography such as for the lumen of ostial lesions or where angiographic images do not visualize lumen segments adequately, such as regions with multiple overlapping arterial segments. It is also used to assess the effects of treatments of stenosis such as with hydraulic angioplasty expansion of the artery, with or without stents, and the results of medical therapy over time.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CAD: Coronary artery disease

CABG: Coronary artery bypass grafting

IVUS: Intra Vascular Arterial Ultrasound

LMCAD: Left main coronary artery disease

PCI: Percutaneous coronary intervention

SUMMARY OF EVIDENCE

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention ⁽⁶⁾

Study Design: The guidelines are based on a comprehensive review of evidence related to PCI, including randomized controlled trials (RCTs), observational studies, meta-analyses, and expert consensus. The writing committee conducted an extensive evidence review through November 2010, with additional references through August 2011. The recommendations are categorized by the Class of Recommendation (COR) and Level of Evidence (LOE), which estimate the size and certainty of the treatment effect.

Target Population: The guidelines target patients undergoing PCI for various clinical scenarios, including stable ischemic heart disease (SIHD), acute coronary syndromes (ACS), and specific anatomical and clinical situations such as chronic total occlusions (CTOs), saphenous vein

grafts (SVGs), bifurcation lesions, aorto-ostial stenoses, calcified lesions, and specific patient populations like the elderly, diabetics, women, and those with chronic kidney disease (CKD) or cardiac allografts.

Key Factors:

Methodology and Evidence Review: The recommendations are evidence-based, with a formal literature review and ranking of evidence supporting each recommendation. The writing committee used evidence-based methodologies developed by the ACCF/AHA Task Force.

PCI Outcomes: Definitions of PCI success include angiographic success, procedural success, and clinical success. Predictors of clinical outcome after PCI include advanced age, diabetes, CKD, ACS, congestive heart failure, and multivessel coronary artery disease (CAD).

PCI Complications: The document discusses various complications associated with PCI, including mortality, myocardial infarction (MI), emergency coronary artery bypass grafting (CABG), stroke, vascular complications, coronary perforation, bleeding, and contrast-induced acute kidney injury (AKI).

Preprocedural Considerations: Recommendations for preprocedural considerations include assessing the risk of contrast-induced AKI, anaphylactoid reactions, statin treatment, bleeding risk, and the use of PCI in hospitals without on-site surgical backup.

Procedural Considerations: Recommendations for procedural considerations include vascular access, PCI in specific clinical situations (UA/NSTEMI, STEMI, cardiogenic shock), revascularization before noncardiac surgery, coronary stents, adjunctive diagnostic devices (FFR, IVUS), adjunctive therapeutic devices (coronary atherectomy, thrombectomy, laser angioplasty, cutting balloon angioplasty, embolic protection devices), and percutaneous hemodynamic support devices.

Postprocedural Considerations: Recommendations for postprocedural considerations include postprocedural antiplatelet therapy, exercise testing, cardiac rehabilitation, secondary prevention, and quality and performance considerations.

2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization ⁽⁷⁾

Study Design: The guidelines are based on a comprehensive literature search conducted from May 2019 to September 2019, which included studies, reviews, and other evidence conducted on human subjects and published in English. The search covered databases such as PubMed, EMBASE, the Cochrane Collaboration, and CINHL Complete. Additional relevant studies published through May 2021 were also considered.

Target Population: The target population includes patients with coronary artery disease (CAD) who are being considered for coronary revascularization. This includes patients with stable ischemic heart disease (SIHD), acute coronary syndromes (ACS), and those undergoing percutaneous coronary intervention (PCI).

Key Factors:

FFR and iFR Use: FFR and instantaneous wave-free ratio (iFR) are physiological methods used to assess lesion significance in patients with angina or angina equivalent

and angiographically intermediate stenoses. FFR is defined as the ratio of maximal blood flow in a region distal to a lesion compared with the normal maximal blood flow of an artery. iFR is an index of lesion severity measured during the wave-free period in diastole.

Clinical Trials and Outcomes: The FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) trial demonstrated that FFR-guided PCI reduced the risk of the composite endpoint of death, myocardial infarction (MI), or urgent revascularization compared with angiography-guided PCI. The DEFINE-FLAIR (Functional Lesion Assessment of Intermediate Stenosis to Guide Revascularization) and iFR-SWEDEHEART (Instantaneous Wave-Free Ratio versus Fractional Flow Reserve in Patients with Stable Angina Pectoris or Acute Coronary Syndrome) trials showed that iFR-guided PCI was noninferior to FFR-guided PCI in terms of clinical outcomes.

Recommendations: FFR or iFR is recommended to guide the decision to proceed with PCI in patients with angiographically intermediate stenoses and undocumented ischemia. PCI should not be performed in stable patients with angiographically intermediate stenoses and FFR >0.80 or iFR >0.89.

Safety and Efficacy: Deferral of PCI when FFR is >0.80 or iFR is >0.89 is associated with low rates of long-term major adverse cardiovascular events (MACE). The use of FFR and iFR has been shown to improve clinical outcomes by reducing unnecessary revascularizations and focusing treatment on lesions that are physiologically significant.

2018 ESC/EACTS Guidelines on myocardial revascularization ⁽⁸⁾

Study Design: The guidelines were developed by the Task Force on myocardial revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). The guidelines were produced after careful consideration of scientific and medical knowledge and the evidence available at the time of their dating. The development process included a comprehensive review of published evidence for diagnosis, management, and prevention of myocardial revascularization, with a critical evaluation of diagnostic and therapeutic procedures, including assessment of the risk-benefit ratio.

Target Population: The guidelines target healthcare professionals involved in the medical care of patients with myocardial revascularization needs. This includes cardiologists, cardiac surgeons, interventional cardiologists, anesthetists, and other specialists. The guidelines aim to assist these professionals in selecting the best management strategies for individual patients with given conditions, taking into account the impact on outcomes as well as the risk-benefit ratio of particular diagnostic or therapeutic means.

Key Factors:

Associations and Councils: The guidelines were developed with contributions from various ESC associations and councils, including the Acute Cardiovascular Care Association (ACCA), European Association of Preventive Cardiology (EAPC), European Association of Cardiovascular Imaging (EACVI), European Association of Percutaneous Cardiovascular Interventions (EAPCI), European Heart Rhythm Association (EHRA), Heart Failure Association (HFA), Council on Cardiovascular Nursing and Allied

Professions, Council for Cardiology Practice, Council on Cardiovascular Primary Care, Council on Stroke, and Council on Valvular Heart Disease.

Diagnostic Tools: The guidelines discuss the use of non-invasive and invasive diagnostic tools to guide myocardial revascularization, including assessment of myocardial ischemia, viability, fractional flow reserve (FFR), and intravascular imaging.

Decision-Making Process: Emphasis is placed on patient information and informed consent, multidisciplinary decision-making (Heart Team), and timing of revascularization.

Revascularization Strategies: The guidelines provide recommendations for revascularization in stable coronary artery disease (SCAD), non-ST-elevation acute coronary syndrome (NSTEMI), ST-segment elevation myocardial infarction (STEMI), heart failure, diabetes, chronic kidney disease, and patients requiring valve interventions.

Procedural Aspects: Detailed recommendations are provided for procedural aspects of coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI), including choice of stent, access site, and antithrombotic treatments.

Volume-Outcome Relationship: The guidelines discuss the impact of operator and institutional volume on outcomes of revascularization procedures and recommend training programs for cardiac surgery and interventional cardiology.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(6–8)

1. **Revascularization Strategies:** All three articles emphasize the importance of revascularization in managing coronary artery disease (CAD). They agree that both coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) are viable options, depending on the patient's specific condition and the complexity of the disease.
2. **Patient Selection:** The articles highlight the necessity of careful patient selection for revascularization procedures. They stress the importance of considering factors such as the severity of CAD, the presence of comorbidities, and the patient's overall health and preferences.

Use of Guidelines: Each article underscores the importance of adhering to clinical guidelines and using a multidisciplinary approach (Heart Team) to make informed decisions about revascularization. This approach ensures that patients receive the most appropriate and effective treatment.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> Added new bullet-point to the General Statement section Checked the Medicare Advantage box in the Applicable Lines of Business table No clinical changes
January 2025	<ul style="list-style-type: none"> This guideline replaces UM 1292 Coronary Intra Vascular Arterial Ultrasound

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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3. Hendel RC, Patel MR, Allen JM, et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF appropriate use criteria methodology update. *J Am Coll Cardiol*. 2013;61(12):1305-1317. doi:10.1016/j.jacc.2013.01.025
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Evolut Clinical Guideline 7276 for Descending Thoracic Aortic Open or Endovascular Surgery

Guideline Number: Evolut_CG_7276	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for procedures on the descending thoracic aorta.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

General Considerations

Thoracic Endovascular Aortic Repair (TEVAR) is preferred over open surgery in all instances where the anatomy is favorable (see **Definitions**). Open surgery is usually reserved for unfavorable anatomy or patients with Connective Tissue Disorders (CTD) or Heritable Thoracic Aortic Diseases (HTAD). When open surgery is requested, the reason must be included in the notes provided. Hybrid procedures may be required especially for thoracoabdominal aneurysms.

Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided.

INDICATIONS (6–8)

Descending Thoracic Aneurysm and Thoracoabdominal Aneurysm

Open surgical repair and TEVAR procedures should be approved for ruptured Descending thoracic aortic aneurysm (DTA) and thoracoabdominal aneurysm and is not dependent on any variable

NOTE: Requests for concomitant subclavian, carotid, or iliac artery bypass should be approved as well as access site, or adjunctive endovascular procedures

- Descending Thoracic Aneurysm (DTA) has been defined by fine-cut (< 0.2 mm) computed tomography angiography (CTA) of the entire aorta and iliac arteries or magnetic resonance angiography (MRA), and **ANY** of the following:
 - DTA ≥ 5.5 cm in low-risk patients
 - DTA ≥ 6.0 cm in high-risk patients
 - DTA ≥ 5.0 cm in women or anyone with Marfan syndrome
 - DTA < 5.0 cm may be appropriate in pregnant women, other HTAD or CTD but the reason must be included in the notes provided
 - DTA < 5.5 cm with:
 - Aneurysm growth of > 0.5 cm in 12 months
 - Symptoms or findings consistent with impending rupture: e.g. but not limited to, appropriate pain, periaortic hematoma, pleural effusion
 - Saccular configuration
 - Mycotic aneurysm
 - Family or personal history of any non-cerebral artery rupture
 - Persistent endoleak after prior Endograft

Other Descending Thoracic Aortic Conditions

This section contains indications regarding descending aortic dissection involving the aortic arch.

- Open surgical repair and TEVAR (Thoracic Endovascular Aortic Repair) procedures for hyperacute or acute pathology unresponsive to supportive medical therapy, including concomitant subclavian, carotid, or iliac artery bypass, as well as referencing access sites and adjunctive endovascular procedures.
- New symptoms or signs of evolving limb, organ or life-saving complications attributable to the aortic pathology or its treatment
- ANY findings consistent with impending rupture:
 - Descending thoracic aortic dissection

- New periaortic hematoma or pleural effusion
- Continued aortic growth ≥ 5 mm in 6 months
- False lumen expansion ≥ 2.2 cm
- Aortic diameter ≥ 5.5 cm
- Endoleak after prior stent
- Intramural hematoma (IMH), or IMH with Penetrating Aortic Ulcer (PAU) with:
 - Progression on follow-up imaging (maximum aortic diameter ≥ 4.5 cm, IMH wall thickness ≥ 10 mm, presence of ulcer-like projections after a period of hypertension control **OR**
 - Concern for rupture as explained in the notes provided
- Isolated Penetrating Aortic Ulcer with
 - Diameter between 13 mm to 20 mm or depth ≥ 10 mm **OR**
 - Concern for rupture as explained in the notes provided
- Aorto-enteric fistula
- Aorto-bronchial fistula
- Infected aorta or aortic grafts
- Aortic tumors
- Kommerell's Diverticulum when diameter exceeds 30 mm or the diameter of the descending aorta adjacent to the diverticulum exceeds 50 mm.
- Symptomatic Aberrant right or left subclavian artery
- Coarctation of the aorta

CODING AND STANDARDS

Codes

33530, 33875, 33877, 33880

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid

☒	Medicare Advantage
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BACKGROUND

Dilation of the descending aorta (TAA) is often detected during other cardiovascular imaging. Descending aortic graft surgery is defined as excision and surgical replacement of the most distal portion of the diseased thoracic aorta with a graft.

Definitions

- **Acute** is 1-14 days since onset of symptoms, whereas **Hyperacute** is < 24 hours since onset of symptoms.
- **Endograft** is a preconstructed graft that is inserted via a remote access site. There are multiple commercial variants where the manufacturers' Instructions For Use (IFU) should be followed. There are surgeon modified grafts, but these should only be used in institutions where the graft has been approved by an Institutional Review Board (IRB) or in a Government approved clinical trial.
- **Favorable anatomy for TEVAR** is anatomy that is consistent with the Instructions For Use (IFU) of the endograft that will be inserted.
- **Heritable Thoracic Aortic Disease (HTAD)** is an aortic condition related to a genetic or heritable condition some of which associated with multisystem features (considered syndromic HTAD) or others with abnormalities limited to the aorta with or without its branches (known as nonsyndromic HTAD). Examples include Marfan, Loeys-Dietz, Turner and Ehlers-Danlos syndromes, Familial Thoracic aortic aneurysms, and possibly bicuspid aortic valve.
- **High risk** is a patient who has significant comorbidities increasing the risk of death, renal failure, stroke, or spinal ischemia and paraplegia.
- **Low risk** is a patient who does not have significant comorbidities.
- **Intramural hematoma** in the wall of the artery without an identifiable communication between the true and false lumens. It is characterized by hyperdense, crescent-shaped hemorrhage within the wall and is best seen on noncontrast enhanced computed tomography.
- **Penetrating aortic ulcer (PAU)** is an atherosclerotic lesion that penetrates the internal elastic lamina of the aortic wall. It was also referred to as ulcer-like projections. It is often associated with IMH.
- **Pregnancy** can significantly impact the disease process and must be taken into consideration when considering surgical intervention.
- **Unfavorable anatomy for TEVAR** is anatomy that would not be suitable for the IFU of any commercially available endograft.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AUC: Appropriate Use Criteria

CTA: Computed Tomography Angiography

CTD: Connective Tissue Disorders

DTA: Descending Thoracic Aneurysm

HTAD: Heritable Thoracic Aortic Disease

IFU: Instructions For Use

IMH: Intramural hematoma

MRA: Magnetic Resonance Angiography

nsHTAD: non-syndromic Heritable Thoracic Aortic Disease

PAU: Penetrating Aortic Ulcer

sHTAD: syndromic Heritable Thoracic Aortic Disease

TEVAR: Thoracic Endovascular Aortic Repair

SUMMARY OF EVIDENCE

2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease ⁽⁶⁾

Study Design: This study is a clinical practice guideline developed by the American Heart Association (AHA) and the American College of Cardiology (ACC) Joint Committee on Clinical Practice Guidelines. It involved a comprehensive literature search from January 2021 to April 2021, including studies, reviews, and other evidence conducted on human subjects published in English from PubMed, EMBASE, the Cochrane Library, CINHL Complete, and other selected databases.

Target Population: The guidelines are intended for clinicians diagnosing and managing patients with aortic disease across multiple clinical presentation subsets, including asymptomatic, stable symptomatic, and acute aortic syndromes.

Key Factors: The guidelines emphasize shared decision-making, institutional interventional volume, and multidisciplinary aortic team expertise in the care of patients with aortic disease.

They provide recommendations for medical therapy, endovascular and surgical treatment, and long-term surveillance.

Society for Vascular Surgery (SVS) and Society of Thoracic Surgeons (STS) reporting standards for type B aortic dissections ⁽⁷⁾

Study Design: This study provides reporting standards for type B aortic dissections developed by the Society for Vascular Surgery (SVS) and the Society of Thoracic Surgeons (STS). It includes a new classification system for practical use and reporting that encompasses the aortic arch.

Target Population: The study focuses on patients with acute type B aortic dissection, which composed approximately 33% of all dissection patients enrolled in the International Registry of Acute Aortic Dissection (IRAD) over a 17-year period.

Key Factors: The document defines complicated vs uncomplicated dissections, high-risk grouping, follow-up criteria, false lumen status, measurement criteria, and definitions of aortic remodeling. It provides a framework for more granular discussions and reporting of aortic dissection.

Society for Vascular Surgery clinical practice guidelines of thoracic endovascular aortic repair for descending thoracic aortic aneurysms ⁽⁸⁾

Study Design: This study is a clinical practice guideline developed by the Society for Vascular Surgery (SVS) for thoracic endovascular aortic repair (TEVAR) for descending thoracic aortic aneurysms (TAA). It involved a systematic review and meta-analysis of observational studies comparing TEVAR and open repair.

Target Population: The guidelines are applicable to patients with descending thoracic aortic aneurysms and other rarer pathologic processes of the descending thoracic aorta.

Key Factors: The guidelines recommend TEVAR over open repair for elective descending thoracic aorta aneurysms due to reduced morbidity, length of stay, and short-term mortality. They emphasize the importance of imaging before, during, and after TEVAR, and provide recommendations for perioperative management, spinal cord protection, and surveillance.

ANALYSIS OF EVIDENCE

Shared Findings ^(6–8)

- **Emphasis on Imaging:** All three articles highlight the importance of accurate imaging techniques for diagnosis and treatment planning. Fine-cut CTA and three-dimensional reconstruction are recommended for precise measurements and planning.
- **Multidisciplinary Approach:** The importance of a multidisciplinary team in managing complex aortic diseases is emphasized across all articles. This approach ensures comprehensive care and optimal outcomes.

- Shared Decision-Making: Shared decision-making involving the patient and a multidisciplinary team is encouraged to determine the best treatment options, considering individual patient factors and preferences.

Conclusion ^(6–8)

The three articles provide comprehensive guidelines and recommendations for the management of descending thoracic aortic diseases, with a focus on imaging, multidisciplinary care, and shared decision-making. While there are shared conclusions regarding the importance of these factors, each article also offers unique insights and recommendations specific to their focus areas, such as classification systems and chronicity definitions for aortic dissections, and specific management strategies for TEVAR.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> ● Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> ● Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices ● Edited text for clarity
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1098 for Descending Thoracic Aortic Graft Surgery <ul style="list-style-type: none"> ○ Guideline name changed to Descending Thoracic Aortic Open or Endovascular Surgery ● Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of



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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7280 for Duplex Scan of Hemodialysis Access

Guideline Number: Evolent_CG_7280	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for duplex scan of hemodialysis (HD) access.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR DUPLEX SCAN OF HEMODIALYSIS ACCESS

- In patients at high risk of AV (arteriovenous) access failure for vascular mapping ⁽⁶⁾ or AV access insufficiency ⁽⁷⁾:
 - Access collapse suggesting poor arterial inflow
 - Poorly matured fistula
 - Loss of thrill

- Palpable “water hammer” pulse
- Abnormal bruit over fistula
- Distal limb ischemia
- Clinical signs of infection
- Perigraft mass, aneurysm, or pseudoaneurysm
- In patient with abnormal fistula function ⁽⁷⁾:
 - Elevated venous pressure greater than 200 mmHg on a 300 cc/min pump
 - Elevated recirculation time of 15% or greater
 - Low urea reduction rate of less than 60%
- For evaluation of suspected central vein occlusion to determine the suitability of AV access creation ⁽⁶⁾
- In patients suspected with clinically significant AV access lesion, further confirmatory evaluation including imaging of the dialysis access circuit within less than two weeks is recommended ⁽⁶⁾
- In cannulation complication for flow direction and proper needle placement in AV access ⁽⁶⁾
- In corroboration with physical examination in confirming AV access infection, AV access aneurysm/pseudoaneurysm, vessel size, presence of stenosis/thrombus, and AV flow parameters (such as flow rate, arterial inflow and venous outflow) ⁽⁶⁾
- In patients with complicated AVG (arteriovenous graft) seroma for careful monitoring ⁽⁶⁾
- As post-operative examination within 6 - 8 weeks and 2 - 4 months after AVF (arteriovenous fistula)/AVG creation to validate maturation of newly created AVF/AVG ⁽⁸⁾
- In patients with prolonged immaturity ≥ 4 weeks of a surgically created AVF, when physical examination is equivocal ^(6,8)

CODING AND STANDARDS

Codes

93990

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow) combines Doppler and conventional ultrasound to see the structure of blood vessels, how the blood is flowing through the vessels, and whether there is any obstruction in the vessels. Combining spectral Doppler analysis and color flow doppler images provide anatomic and hemodynamic information.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AV: Arteriovenous

AVF: Arteriovenous fistula

AVG: Arteriovenous graft

SUMMARY OF EVIDENCE

KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update ⁽⁶⁾

Study Design: The guideline update was conducted by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI). The update involved a comprehensive review of the literature, including more than 4,600 articles, of which 286 were included in the evidence tables used to develop the 26 guideline sections. The evidence review was independently conducted using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.

Target Population: The guidelines are intended for multidisciplinary practitioners who care for chronic kidney disease (CKD) patients and their vascular access. This includes nephrologists, surgeons, interventional radiologists, nurses, and other healthcare professionals involved in the management of hemodialysis vascular access.

Key Factors:

End-Stage Kidney Disease (ESKD) Life-Plan: The guidelines introduce the concept of an individualized ESKD Life-Plan, which maps out a comprehensive strategy for dialysis modalities and vascular access for the lifetime of the patient.

Vascular Access Choice: The guidelines provide recommendations on the choice of vascular access, including arteriovenous fistulas (AVFs), arteriovenous grafts (AVGs), and central venous catheters (CVCs), based on patient circumstances and preferences.

Vascular Access Types and Locations: The guidelines discuss the indications for use, types, and locations of vascular access, emphasizing a patient-centered approach.

Preoperative and Postoperative Care: The guidelines include recommendations for preoperative vessel mapping, postoperative evaluation, and interventions to enhance AVF maturation and prevent complications.

Complications and Management: The guidelines address the prevention, monitoring, and treatment of complications related to vascular access, including infections, thrombosis, and stenosis.

Duplex Ultrasound Evaluation of Hemodialysis Access: A Detailed Protocol ⁽⁷⁾

Study Design: The study provides a detailed protocol for the performance and interpretation of duplex ultrasound evaluation of hemodialysis access. It is a review article that consolidates the authors' experiences in both the vascular laboratory and the operating room in the creation and maintenance of hemodialysis access.

Target Population: The target population for this study includes hemodialysis patients who require the creation and maintenance of arteriovenous access (AVA) for dialysis. This includes patients who are obese, have had multiple previous access surgeries, or have suspected arterial or venous disease.

Key Factors

Anatomical Facts: The upper extremities are most commonly used for dialysis access, with AVA created by connecting a vein to an artery (AV fistula or AVF) or by interposing a conduit between an artery and a vein (AV graft or AVG).

Indications for Ultrasound Examination: The study outlines various clinical indications for performing duplex ultrasound, such as difficult cannulation, thrombus aspiration, elevated venous pressure, and clinical signs of AV access insufficiency.

Instrumentation: The examination is performed using an ultrasound duplex imager with pulsed wave and color flow Doppler capability and Doppler spectral analysis.

General Considerations: Accurate results require pulsed Doppler interrogation/sampling at an angle of 60 degrees or less. The study emphasizes the importance of proper insonation angles and sample volume placement.

Procedure: The protocol includes detailed steps for scanning the graft or fistula, documenting waveforms, and measuring peak systolic velocity (PSV) and end-diastolic velocity (EDV).

Diagnostic Criteria: The study provides criteria for diagnosing stenosis and other abnormalities based on duplex ultrasound findings.

Documentation and Reporting: The study highlights the importance of archiving images and data records, and creating a final report within 24 hours of the examination.

Editor's Choice – Vascular Access: 2018 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS) ⁽⁸⁾

Study Design: The study design is centered around the development of clinical practice guidelines by the European Society for Vascular Surgery (ESVS) for vascular access in patients undergoing hemodialysis. The guidelines were formulated by a writing committee composed of vascular surgeons, nephrologists, radiologists, and clinical nurses from various European countries and institutions. The committee performed a systematic literature search in the MEDLINE, EMBASE, and COCHRANE Library databases, focusing on peer-reviewed published literature, randomized clinical trials, meta-analyses, systematic reviews, and well-conducted observational studies.

Target Population: The target population includes patients with chronic kidney disease (CKD) stage 5, who require renal replacement therapy such as hemodialysis. The guidelines aim to assist physicians in selecting the best management strategies for patients needing vascular access or dealing with pathologies derived from vascular access.

Key factors:

- Methodology and grading of recommendations

- Epidemiology of CKD stage 5 and end-stage renal disease (ESRD)

- Clinical decision-making for vascular access, including the choice of type, timing of referral, and selection of modality

- Pre-operative imaging and assessment techniques

- Technical aspects of vascular access creation, including venous preservation, arm exercises, hydration, prophylactic antibiotics, and surgical techniques

- Surveillance and monitoring of vascular access, including access maturation, cannulation techniques, and access care

Management of late complications such as aneurysms, infections, stenosis, thrombosis, and central venous occlusive disease

Complex or tertiary hemodialysis vascular access options

ANALYSIS OF EVIDENCE

Shared Conclusions ^(6–8)

Preference for AVFs: All three articles emphasize the preference for autogenous AVFs over AVGs and CVCs due to lower complication rates and better long-term outcomes.

Importance of Monitoring and Surveillance: Regular monitoring and surveillance are crucial for detecting access dysfunction and preventing complications.

Management of Complications: Effective management of complications such as infections, thrombosis, and stenosis is essential for maintaining access patency.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> Added new bullet-point to the General Statement section Checked the Medicare Advantage box in the Applicable Lines of Business table Added a Summary of Evidence and Analysis of Evidence
December 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1079 Duplex Scan of Hemodialysis Access Updated indications for Duplex Scan of Hemodialysis Access Removed Special Note and Limitation sections Updated references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolut Clinical Guideline 7281 for Guideline Directed Medical Therapy – Heart Failure and Coronary Artery Disease

Guideline Number: Evolut_CG_7281		
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Original Date: May 2024	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Heart failure with reduced ejection fraction (HFrEF) is a complex condition that can arise from multiple factors, including coronary artery disease, hypertension, myocardial infarction, valvular heart disease, and cardiomyopathies. These underlying conditions collectively impair the heart's ability to effectively pump blood, leading to a reduction in ejection fraction. Similarly, heart failure with preserved ejection fraction (HFpEF) presents with comparable symptoms but is distinguished by a left ventricular ejection fraction (LVEF) of 50% or higher.

Medical management is of utmost importance in addressing both HFrEF and HFpEF, aiming to alleviate symptoms, improve quality of life, and extend lifespan. Medications play a crucial role in reducing cardiac workload, enhancing cardiac function, and managing fluid overload. Before considering invasive procedures, the administration of medications is essential to stabilize the patient's condition, optimize cardiac function, and minimize the risks associated with such interventions.

Guideline-Directed Medical Therapy (GDMT) serves as the cornerstone of management for both heart failure and coronary artery disease (CAD). Evidence-based guidelines universally recommend GDMT for individuals diagnosed with CAD, particularly as a primary treatment for stable CAD and as a crucial component of secondary prevention following coronary revascularization procedures like percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). GDMT has been associated with a significant reduction in death rates and the risk of myocardial infarction (MI), and in some cases, its impact on mortality reduction may even surpass that of selecting a specific revascularization method. Notably, GDMT for CAD intersects with recommendations for heart failure management, emphasizing the importance of comprehensive and integrated care for individuals with these conditions.

Purpose

GDMT must be administered before further consideration of additional imaging and/or initial or additional procedures. This document outlines the requirements based on the current ACC and AHA recommendations.

Clinical Reasoning

The current ACC/AHA clinical practice guidelines have established the requirements for pharmacologic therapy considered for patients with chronic CAD and/or NYHA Class II-IV. When applicable, optimal GDMT shall focus on therapies with Class I recommendations that have demonstrated reductions in morbidity, mortality, and improvements in patient quality of life, unless specified. The beneficial effects of medications can become apparent within weeks of initiation. These drugs have additive effects and in most cases the effects are dose related. As a result, GDMT stipulates that all medications be initiated and then titrated to the maximal tolerated dose (or a target dose) as quickly as possible. ^(1–5)

INDICATIONS

Guideline Directed Medical Therapy (GDMT) for HFrEF (non-ischemic) ^(6,7)

Documentation must be provided of all the following:

- **NYHA functional class (see Definitions)**
- **The report of the last modality having measured the ejection fraction (EF)**
 - MUGA
 - Echocardiography
 - Left Ventriculogram
 - Nuclear stress test (SPECT)
 - Cardiac MRI
 - Cardiac CT
 - Cardiac PET
- **An up-to-date list of heart failure medications and their dosages (see Definitions).**

The following medications need to be addressed along with any intolerance or reason a medication cannot be titrated (when titration is indicated) to maximal dosing (i.e. renal dysfunction, side effects, blood pressure, heart rate limitations, etc.)

 - ACE inhibitor/ARB OR angiotensin receptor neprilysin inhibitor (ARNI)
 - Beta blocker (bisoprolol, carvedilol, and metoprolol succinate)
 - MRA
 - SGLT2 Inhibitor
- **Last vital signs measured while on medications**
 - Vital signs must be reasonably controlled (i.e., BP <140/90mmHg, HR <100)
- **Documentation of Time since GDMT has been optimized:**

- Patients diagnosed with non-ischemic heart failure with reduced ejection fraction (HFrEF) should be maintained on maximal tolerated GDMT **for a period of 12 weeks** before moving forward with any additional testing or invasive/interventional procedures.

Guideline Directed Medical Therapy (GDMT) for HFrEF (Ischemic) ^(6,7)

ISCHEMIC CARDIOMYOPATHY: In addition to the recommendations for GDMT in heart failure for non-ischemic cardiomyopathy (SEE ABOVE), those with suspected or known CAD should additionally document all of the following:

- **The report of the last modality having demonstrated coronary disease**
 - Non-Invasive testing
 - Nuclear stress test (SPECT)
 - Stress Echocardiography
 - Coronary CTA
 - Cardiac PET scan
 - Cardiac MRI
- Within the up-to-date list of medications and their dosages, as stated for heart failure in non-ischemic cardiomyopathy, **additional medications should document:**
 - Antiplatelet Therapy
 - Statin Therapy
- Patients diagnosed with ischemic heart failure with reduced ejection fraction (HFrEF) should be maintained on maximal tolerated GDMT for a period time before moving forward with any additional testing or invasive/interventional procedures.
 - The following time periods have been established post MI:
 - **Non-revascularized: 40 days**
 - **Revascularized: 12 weeks**

Guideline Directed Medical Therapy (GDMT) for HFpEF ^(7,8)

Heart Failure with preserved Ejection Fraction (HFpEF) is diagnosed clinically when the Left Ventricular Ejection Fraction (LVEF) is equal to or greater than 50%. It should be noted that HFpEF is not interchangeable with diastolic dysfunction, as the presence of diastolic dysfunction on echocardiogram lacks the specificity required for clinical diagnosis or condition. A comprehensive diagnostic evaluation is warranted to ascertain underlying etiologies that may mimic HFpEF. Following confirmation of HFpEF, therapeutic interventions should prioritize addressing comorbidities and adhering to guideline-directed medical therapy (GDMT) to optimize patient outcomes, including enhancing quality of life, reducing hospitalizations, and improving survival rates. This guideline is specifically dedicated to delineating the medical management strategies post-confirmation of HFpEF diagnosis (GDMT).

Documentation must be provided of all of the following:

- **NYHA functional class (see Definitions)**
- **The report of the last modality having measured the Ejection Fraction**
 - MUGA
 - Echocardiography
 - Left Ventriculogram
 - Nuclear stress test (SPECT)
 - Cardiac MRI
 - Cardiac CT
 - Cardiac PET
- **Documentation that other conditions that mimic HFpEF have been considered**
- **An up-to-date list of heart failure medications and their dosages (see Definitions).**
The following medication needs to be addressed along with any intolerance or reason it cannot be titrated (when titration is indicated) to maximal dosing (i.e. renal dysfunction, side effects, blood pressure, heart rate limitations, etc.)
 - SGLT2 Inhibitor
- **Last Vital signs measured while on medications**
 - Vital signs must be reasonably controlled (i.e., BP <140/90mmHg)
- **Documentation of Time since GDMT has been optimized**

Guideline Directed Medical Therapy (GDMT) for CAD with Preserved Ejection Fraction ⁽⁹⁾

All of the following must be documented for GDMT:

- **Canadian Class for angina (see Definitions) or description of ongoing symptoms despite medications**
- **The report of the last modality having demonstrated coronary disease**
 - Non-Invasive testing
 - Nuclear stress test (SPECT)
 - Stress Echocardiography
 - Coronary CTA
 - Cardiac PET scan
 - Cardiac MRI
- **An up-to-date list of anti-anginal and risk modifying medications and their dosages (see Definitions).** At least two of the following medications need to be

addressed along with any intolerance or reason at least two medications cannot be titrated (when titration is indicated) to maximal dosing (i.e. renal dysfunction, side effects, blood pressure, heart rate limitations, etc.)

- ACE inhibitor/ARB OR angiotensin receptor neprilysin inhibitor (ARNI)
- Beta blocker if between 0- 3 years from MI (myocardial infarction)
- Nitrates
- Calcium channel blockers
- Ranolazine
- **Last vital signs measured while on medications**
 - Vital signs must be reasonably controlled (i.e., BP <140/90mmHg, HR <100)
- **Documentation of Time since GDMT has been optimized**
- **Exceptions for GDMT documentation:** The following **does not require** GDMT documentation:
 - Class I indications for revascularization inclusive of high-risk non-invasive testing, or prior invasive testing demonstrating high risk left main (LM) CAD and multivessel CAD associated with diabetes.

CODING AND STANDARDS

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- **Heart failure with reduced ejection fraction (HFrEF)**, also known as systolic heart failure, occurs when the left ventricle of the heart is unable to pump blood efficiently. In this condition, the heart's pumping function is weakened, resulting in less blood being

ejected into the body. HFrEF is characterized by a left ventricular ejection fraction (LVEF) of $\leq 40\%$. Patients with HFrEF may experience symptoms such as fatigue, shortness of breath, and fluid retention.

- **Heart failure with preserved ejection fraction (HFpEF)** occurs when the heart's main pumping chamber (left ventricle) has a normal or near-normal ejection fraction (EF). In HFpEF, the EF is $\geq 50\%$. As opposed to HFrEF, the hallmark of HFpEF is stiffening of the heart muscle, particularly in the left ventricle. This stiffness impairs the heart's ability to relax and fill with blood properly causing similar symptoms as HFrEF.
- **Guideline-Directed Medical Therapy (GDMT):** Evidence-based treatment regimens recommended by clinical practice guidelines for managing specific medical conditions. These guidelines are developed by expert panels and professional organizations to provide standardized, effective, and safe approaches to patient care. GDMT typically includes medications, lifestyle modifications, and other interventions that have demonstrated efficacy in improving patient outcomes. Evidence based pharmacologic therapies used in treatment of HFrEF have demonstrated a reduction in morbidity, mortality, and rate of hospitalization. Efficacious therapies used in HFpEF are directed towards the treatment of the underlying condition (e.g., HTN, AF) rather than on HF. Unless otherwise indicated, class 1 level of evidence will be used as the basis of the recommendations outlined in this document
- **American College of Cardiology/American Heart Association (ACC/AHA) Stages of HF ⁽⁷⁾:**
 - Stage A: At high risk for HF but without structural heart disease or symptoms of HF
 - Stage B: Structural heart disease but without signs or symptoms of HF
 - Stage C: Structural heart disease with prior or current symptoms of HF
 - Stage D: Refractory HF requiring specialized interventions
- **New York Heart Association (NYHA) Functional Classification ⁽⁸⁾:**
 - Class I: No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF
 - Class II: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF
 - Class III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms of HF
 - Class IV: Unable to perform any physical activity without symptoms of HF, or symptoms of HF at rest

Medications HFrEF ⁽⁷⁾

Drug Class	Starting dose	Target dose
Beta-Blockers		
Bisoprolol	1.25 mg once daily	10 mg once daily
Carvedilol	3.125 mg twice daily	25 mg twice daily for weight <85 kg and 50 mg twice daily for weight ≥85 kg
Metoprolol succinate	12.5–25 mg daily	200 mg daily
ARNIs		
Sacubitril/valsartan	24/26 mg–49/51 mg twice daily	97/103 mg twice daily
ACEIs		
Captopril	6.25 mg 3× daily	50 mg 3× daily
Enalapril	2.5 mg twice daily	10–20 mg twice daily
Lisinopril	2.5–5 mg daily	20–40 mg daily
Ramipril	1.25 mg daily	10 mg daily
ARBs		
Candesartan	4–8 mg daily	32 mg daily
Losartan	25–50 mg daily	150 mg daily
Valsartan	40 mg twice daily	160 mg twice daily
Aldosterone antagonists		
Eplerenone	25 mg daily	50 mg daily
Spirolactone	12.5–25 mg daily	25–50 mg daily
SGLT2 inhibitors		
Dapagliflozin	10 mg daily	10 mg daily
Empagliflozin	10 mg daily	10 mg daily
Vasodilators		
Hydralazine	25 mg 3× daily	75 mg 3× daily
Isosorbide Dinitrate	20 mg 3× daily	40 mg 3× daily
Fixed-dose combination	20 mg/37.5 mg (1 tab) 3× daily	2 tabs 3× daily
<p>ACC = American College of Cardiology; ACEI = angiotensin-converting enzyme inhibitor; AHA = American Heart Association; ARB = angiotensin receptor blocker; ARNI = angiotensin receptor-neprilysin inhibitor; GDMT = guideline-directed medical therapy; HF = heart failure; HFrEF = heart failure with reduced ejection fraction; HFSA = Heart Failure Society of America; SGLT2 = sodium-glucose cotransporter-2.</p>		

Medications HFpEF ⁽⁷⁾

Drug Class	Starting dose	Target dose
SGLT2is		
Dapagliflozin	10 mg daily	10 mg daily
Empagliflozin	10 mg daily	10 mg daily
Aldosterone antagonists		
Spironolactone	25 mg daily	50 mg daily
ARNIs		
Sacubitril/valsartan	24 mg/26 mg twice daily	97 mg/103 mg twice daily
ARBs		
Candesartan	4 mg to 8 mg daily	32 mg daily
ARB = angiotensin receptor blocker; ARNI = angiotensin receptor–neprilysin inhibitor; GDMT = guideline-directed medical therapy; HFpEF = heart failure with preserved ejection fraction; SGLT2 = sodium-glucose cotransporter-2.		

- **The Canadian Cardiovascular Society (CCS)** provides a grading system for angina pectoris, which helps classify the severity of angina based on the patient's limitations during physical activity. Here are the four classes in the CCS angina grading scale ⁽¹⁰⁾:
 - **Class I:** Patients experience angina only during strenuous or prolonged physical activity (such as walking or climbing stairs). Ordinary physical activity does not cause angina
 - **Class II:** Patients have slight limitation of ordinary activity. Angina occurs during vigorous physical activity, rapid walking, walking uphill, after meals, in cold or windy conditions, under emotional stress, or only during the few hours after awakening. They can still walk more than two blocks on level ground and climb more than one flight of ordinary stairs at a normal pace and in normal conditions
 - **Class III:** Patients experience marked limitation of ordinary physical activity. They can walk only one or two blocks on level ground and climb one flight of stairs at a normal pace and in normal conditions
 - **Class IV:** Patients have inability to carry on any physical activity without discomfort. Anginal symptoms may even be present at rest.
- **Non-Pharmacological Therapy** – While not explicitly listed as a prerequisite in this guideline, it is still important to mention for the sake of completeness, other crucial facets of treatment

of treatment ^(7,8):

- Smoking and alcohol cessation counseling
- Weight management- restrict fluid intake if serum sodium is low; reduce weight if obese
- Lifestyle modifications (e.g., diet, exercise program)
- Limit dietary sodium intake (1500 mg/day for most patients with stage A and B HF; < 3g/day in patients with stage C and D HF)
- Control diabetes mellitus (with DM- HbA1c level \leq 6.5%) and hypertension (HTN- BP goal < 130/80 mm Hg)
- Cardiac rehabilitation: patient evaluation and monitoring to support drug titration, monitor symptoms, improve health status, and increase exercise tolerance should continue after start of GDMT at least monthly for 3 months and every 3 months thereafter (more frequent follow up may be necessary for select patients)

SUMMARY OF EVIDENCE

2024 ACC Expert Consensus Decision Pathway for Treatment of Heart Failure With Reduced Ejection Fraction ⁽⁶⁾

Study Design: This document is an expert consensus decision pathway for the treatment of heart failure with reduced ejection fraction (HFrEF). It was approved by the American College of Cardiology Clinical Policy Approval Committee in February 2024.

Target Population: The target population includes individuals with HFrEF, defined as heart failure with LVEF \leq 40%.

Key Factors:

Initiation and Titration of GDMT: The document provides detailed recommendations on how to initiate, add, or switch to evidence-based GDMT for HFrEF, including angiotensin receptor-neprilysin inhibitors, SGLT inhibitors, ivabradine, and vericiguat.

Clinical Assessment: It discusses the importance of clinical assessment, including imaging data, biomarkers, and filling pressures, to guide GDMT.

Referral to HF Specialist: The document outlines when to refer patients to an HF specialist and how to optimize care coordination.

Adherence: It provides strategies to improve medication adherence and manage patients' costs and access to HF medications.

Special Populations: The document includes recommendations for specific patient cohorts, such as African-American populations, older adults, and patients living with frailty.

2023 ACC Expert Consensus Decision Pathway on Management of Heart Failure With Preserved Ejection Fraction ⁽⁸⁾

Study Design: This document is an expert consensus decision pathway on the management of heart failure with preserved ejection fraction (HFpEF). It was approved by the American College of Cardiology Clinical Policy Approval Committee in March 2023.

Target Population: The target population includes individuals with HFpEF, which is defined as heart failure with left ventricular ejection fraction (LVEF) $\geq 50\%$. The document also addresses specific challenges in the management of women with HFpEF.

Key Factors:

Diagnosis: The document discusses the universal definition of HF, differential diagnosis of dyspnea and edema, and HFpEF diagnostic scoring systems.

Management: It covers guideline-directed medical therapy (GDMT) for HFpEF, including the use of sodium-glucose cotransporter-2 inhibitors, mineralocorticoid antagonists, angiotensin receptor-neprilysin inhibitors, and angiotensin receptor blockers.

Nonpharmacological Management: The document includes recommendations for exercise, calorie restriction, and pulmonary artery pressure monitoring.

Multidisciplinary Considerations: It emphasizes the importance of a team-based approach to care and transitions of care.

2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease ⁽⁹⁾

Study Design: The document is a clinical practice guideline for the management of patients with chronic coronary disease (CCD). It was developed by the American Heart Association (AHA) and the American College of Cardiology (ACC) Joint Committee on Clinical Practice Guidelines, in collaboration with and endorsed by several other organizations.

Target Population: The target population includes patients with chronic coronary disease, which encompasses a range of conditions such as obstructive and nonobstructive coronary artery disease (CAD), ischemic heart disease diagnosed by noninvasive testing, and chronic angina syndromes.

Key Factors:

Diagnosis and Risk Stratification: The guideline emphasizes the importance of comprehensive risk stratification, incorporating noninvasive and invasive testing results to classify patients' risk levels and guide therapeutic decision-making.

Management: It covers a wide range of management strategies, including lifestyle modifications, pharmacological treatments, and revascularization procedures. Specific recommendations are provided for the use of statins, antiplatelet therapy, beta-blockers, renin-angiotensin-aldosterone system inhibitors, and other medications.

Special Populations: The guideline addresses the management of CCD in special populations, including women, older adults, patients with chronic kidney disease, and those with concurrent conditions such as diabetes and heart failure.

Nonpharmacological Interventions: Recommendations include the use of cardiac rehabilitation, physical activity, and dietary modifications to improve cardiovascular outcomes.

Multidisciplinary Care: The importance of a team-based approach to care, involving cardiologists, primary care providers, and other specialists, is emphasized to optimize patient outcomes.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(6,8,9)

All three documents emphasize the importance of GDMT in managing heart failure and chronic coronary disease. They highlight the need for comprehensive risk stratification, multidisciplinary care, and the use of evidence-based pharmacological treatments. Additionally, they stress the importance of nonpharmacological interventions, such as lifestyle modifications and cardiac rehabilitation, to improve patient outcomes.

Differing Conclusions ^(6,8,9)

- **Target Population:** While Virani et al 2023 focuses on chronic coronary disease, Kittleson et al 2023 and Maddox et al 2024 focus on heart failure, with Kittleson et al addressing HFpEF and Maddox et al addressing HFrEF.
- **Management Strategies:** Virani et al 2023 provides a broader range of management strategies for chronic coronary disease, including revascularization procedures, whereas Kittleson et al 2023 and Maddox et al 2024 focus more on specific pharmacological treatments for heart failure.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> • Added third bullet to General Information • Added Summary of Evidence and Analysis of Evidence
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1462 for Guideline Directed Medical Therapy (GDMT) for Heart Failure and Coronary Artery Disease (CAD)

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7282 for Atrial Fibrillation Ablation

Guideline Number: Evolent_CG_7282	<u>Applicable Codes</u>	
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Original Date: January 2025	Last Revised Date: July 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Define indications for approval of ablation in the management of atrial fibrillation.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR CATHETER ABLATION OF ATRIAL FIBRILLATION (AF) ^(6–8)

Failed Antiarrhythmic Therapy

Catheter ablation is recommended or reasonable for any of the following that are refractory or intolerant to at least one Class I or III antiarrhythmic medication:

- Symptomatic paroxysmal AF
- Symptomatic persistent AF

- Symptomatic long standing persistent AF

First Line Therapy for Symptomatic Atrial Fibrillation

Catheter ablation is recommended or reasonable for the following patients:

- Symptomatic paroxysmal or persistent atrial fibrillation who have not undergone trial(s) of class I or III antiarrhythmic therapy
- Long-standing persistent atrial fibrillation (defined as continuous AF for >12 months) who have not undergone trial(s) of class I or III antiarrhythmic therapy

Heart Failure

Catheter ablation is beneficial or reasonable in the following patients:

- AF and left ventricular systolic dysfunction (LVEF) related to arrhythmia-mediated cardiomyopathy
- AF and heart failure with reduced ejection fraction regardless of previous antiarrhythmic drug failure or intolerance

Coexistent Rhythm Disorders

Catheter ablation is reasonable in the following patients:

- Supraventricular tachycardia with AF when the former is considered the main trigger of the latter
- AF and symptomatic bradycardia or prolonged sinus pauses upon AF termination

Other Risk Factors or Diseases

Catheter ablation is reasonable in patients with hypertrophic cardiomyopathy after careful consideration of anticipated clinical benefit, associated risk of procedural complications, and potential need for more than one procedure

INDICATIONS FOR RECURRENCE OF ATRIAL FIBRILLATION OR ATRIAL TACHYCARDIA (AT) AFTER ABLATION ^(6,8)

- Early recurrence after AF ablation has been defined as any recurrence of AF or AT lasting 30 seconds during the first 3 months of follow-up

NOTE: 50% of early tachycardias are reentrant atrial tachycardias, and 49% resolve spontaneously over the first year. They should be considered for cardioversion, especially within 30 days of arrhythmia onset before treated with Class III antiarrhythmic therapy unless intolerable symptoms persist after this therapy is attempted. (Class Ic

drugs are relatively contraindicated, as they tend to promote and prolong these reentrant arrhythmias).

- Late term recurrence has been defined as any recurrence of AF or AT lasting 30 seconds between 3 and 12 months after AF; mapping and ablation of these rhythm disturbances is recommended

INDICATIONS FOR SURGICAL ABLATION OF ATRIAL FIBRILLATION (6,8)

Concomitant “Open” Surgical Ablation

Concomitant “Open” surgical ablation (such as mitral or tricuspid valve surgery) for patients with any of the following:

- Symptomatic AF, refractory or intolerant to at least one Class I or III antiarrhythmic drug, and any form of AF (paroxysmal, persistent, or long-standing persistent), surgical ablation is recommended
- Symptomatic AF prior to a trial of antiarrhythmic therapy with a Class I or III antiarrhythmic drug and any form of AF, surgical ablation is recommended

Concomitant “Closed’ Ablation

Concomitant “Closed’ Ablation (coronary artery bypass graft (CABG), aortic valve surgery, etc.) for patients with any of the following:

- Symptomatic AF refractory or intolerant to at least one Class I or III antiarrhythmic drug and any form of AF, surgical ablation is recommended
- Symptomatic AF prior to a trial of antiarrhythmic therapy with a Class I or III antiarrhythmic drug and any form of AF, surgical ablation is reasonable

Stand Alone and Hybrid (catheter- and surgical-) Ablation

- Stand Alone and/or Hybrid surgical ablation for patients (after review of the relative safety and efficacy of catheter ablation versus a stand-alone surgical approach):
 - Who have failed one or more attempts at catheter ablation
 - Who are intolerant or refractory to antiarrhythmic drug therapy and prefer a surgical approach

INDICATIONS FOR ATRIOVENTRICULAR (AV) NODAL ABLATION AND PERMANENT PACEMAKER IMPLANTATION ^(6,8)

- Implantation of a permanent pacemaker, followed by ablation of the AV node, should be reserved for patients in whom rhythm control with antiarrhythmic drugs or catheter ablation, and rate control with pharmacological therapy has failed or is contraindicated or has been refused by the patient ⁽⁷⁾
- AV nodal ablation is approvable in patients with atrial fibrillation and with existing bi-ventricular pacing systems, to increase the percentage of resynchronized pacing and efficacy of the pacing system

CODING AND STANDARDS

Codes

93623, 93650, 93653, 93656, 93657

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Pulmonary vein isolation (PVI) is the cornerstone of atrial fibrillation (AF) ablation, and the primary target endpoint for first-time AF ablation. Because the substrate for atrial fibrillation is typically left atrial, transseptal puncture for access to the left atrium is required in all AF ablation procedures. ^(6,7)

Risk of atrial fibrillation does not increase appreciably in the setting of heart failure or advancing age (up to age 80).

The most common energy source for atrial fibrillation ablation is radiofrequency (RF) energy. In recent years, cryoablation using a balloon catheter has become a reliable alternative to RF

energy. Other techniques for ablation include laser balloon systems, multielectrode arrays and balloon-based ultrasound ablation systems. ⁽⁶⁾

Patients with ostensibly asymptomatic atrial fibrillation are often discovered to have been symptomatic once a “trial of sinus rhythm” after cardioversion has been undertaken. Based on this observation, AHA/ACC/HRS guidelines recommend ablation of atrial fibrillation in asymptomatic patients after careful discussion of the risks, benefits, and alternatives of this approach. ⁽⁶⁾

Atrio-Esophageal Fistula (AEF) is a rare but life-threatening complication of atrial fibrillation ablation. After ablation, symptoms and findings suggesting the possibility of evolving AEF include chest pain, painful swallowing, fever, leukocytosis, TIA, and/or stroke typically occurring between 1- and 3-weeks post ablation. If esophageal injury is suspected, CT imaging with intravenous and water- soluble oral contrast is recommended. Surgical resection of the fistula may be lifesaving. ⁽⁶⁾

Pacemaker implantation followed by AV nodal ablation (“ablate-and-pace”) is typically performed in older patients. It has the advantage of improving symptoms related to irregular and rapid heartbeats and may improve LVEF in patients with tachycardia-associated cardiomyopathy. It exposes the patient to the potential complications of long-term indwelling hardware and pacemaker-dependency. ⁽⁷⁾

Definitions

- Long-standing atrial fibrillation: continuous atrial fibrillation for greater than 12 months
- Class I antiarrhythmic therapy: Produce Na⁺ channel block and reduce AP phase 0 slope and overshoot with variable effects on AP duration (APD) and effective refractory period (ERP) ⁽⁹⁾
- Class II antiarrhythmic therapy: Class II drugs, comprising β -adrenergic inhibitors, reduce sino-atrial node (SAN) pacing rates and slow atrioventricular node (AVN) conduction ⁽⁹⁾
- Class III antiarrhythmic therapy: Comprising K⁺ channel blockers, prolong AP phase 3 repolarization and lengthen ERP ⁽⁹⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ACC: American College of Cardiology

AEF: Atrio-Esophageal Fistula

AF: Atrial fibrillation
AHA: American Heart Association
AP: Action potential
APD: Action potential duration
AT: Atrial tachycardia
AUC: Appropriate use criteria
AV: Atrioventricular
AVN: Atrioventricular node
CABG: Coronary artery bypass graft
CT: Computed tomography
ERP: Effective refractory period
HRS: Heart Rhythm Society
LVEF: Left ventricular ejection fraction
PVI: Pulmonary vein isolation
RF: Radiofrequency
RFA: Radiofrequency ablation
TIA: Transient ischemic attack

SUMMARY OF EVIDENCE

2024 European Heart Rhythm Association/Heart Rhythm Society/Asia Pacific Heart Rhythm Society/Latin American Heart Rhythm Society expert consensus statement on catheter and surgical ablation of atrial fibrillation ⁽⁶⁾

Study Design: This document is an expert consensus statement developed by multiple cardiac electrophysiology societies, including the European Heart Rhythm Association, Heart Rhythm Society, Asia Pacific Heart Rhythm Society, and Latin American Heart Rhythm Society. It provides practical guidance and standards for the selection and management of patients undergoing catheter or surgical ablation of atrial fibrillation (AF).

Target Population: The target population includes patients considered for or undergoing catheter or surgical AF ablation.

Key Factors:

- **Pathophysiology:** The document discusses the mechanisms of AF initiation and maintenance, including the role of triggers, focal and rotational activity, multi-wavelet reentry, and endocardial-epicardial asynchrony.
- **Anatomical Considerations:** It covers the anatomy relevant to catheter ablation, such as pulmonary veins, epicardial connections, interatrial septum, left atrial musculature, coronary sinus, vein of Marshall, superior vena cava, autonomic ganglionated plexi,

pericardial reflections, phrenic nerves, and esophagus.

- Indications for Ablation: The document provides recommendations for catheter ablation in various patient groups, including those with AF-related symptoms, heart failure, coexistent rhythm disorders, and other risk factors.
- Procedural Management: It includes detailed sections on preprocedural management, mapping and ablation tools, procedural techniques, postprocedural management, and ablation outcomes.

2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation ⁽⁸⁾

Study Design: This document is a clinical practice guideline developed by the American College of Cardiology, American Heart Association, American College of Clinical Pharmacy, and Heart Rhythm Society. It provides recommendations for the diagnosis and management of atrial fibrillation.

Target Population: The target population includes patients with atrial fibrillation.

Key Factors:

- Epidemiology: The guideline discusses the prevalence, incidence, morbidity, and mortality associated with AF.
- Risk Factors: It identifies various risk factors for AF, including demographic, anthropometric, cardiovascular, noncardiac conditions, biomarkers, and genetic markers.
- Clinical Evaluation: Recommendations for basic clinical evaluation, including transthoracic echocardiogram, laboratory testing, and targeted testing for associated conditions.
- Management: The guideline covers lifestyle and risk factor modification, prevention of thromboembolism, rate control, rhythm control, and management of patients with heart failure.
- Special Populations: It provides recommendations for specific patient groups, such as athletes, pregnant women, and those with congenital heart disease.

Atrial fibrillation: better symptom control with rate and rhythm management ⁽⁷⁾

Study Design: This review article discusses the management of atrial fibrillation symptoms through rate and rhythm control strategies.

Target Population: The target population includes patients with atrial fibrillation experiencing significant symptoms.

Key Factors:

- Symptom Control: The review emphasizes the importance of symptom control in AF management and discusses the hemodynamic consequences of AF that contribute to symptom burden.

- Rate Control: It covers various rate control options, including beta-blockers, calcium channel blockers, digoxin, and combination therapies.
- Rhythm Control: The review discusses rhythm control options, including cardioversion, antiarrhythmic drugs, and catheter ablation.
- Catheter Ablation: It highlights the efficacy of catheter ablation in improving symptoms and quality of life, and discusses the procedural risks and benefits.
- Shared Decision Making: The importance of shared decision making in choosing the appropriate treatment strategy for individual patients.

ANALYSIS OF EVIDENCE

Shared Findings ^(6–8):

- All three articles agree on the importance of rhythm control in managing AF, particularly for symptomatic patients.
- They all emphasize the role of catheter ablation as an effective treatment option for maintaining sinus rhythm and improving quality of life.
- The articles highlight the need for individualized treatment plans based on patient characteristics, comorbidities, and preferences.

Conclusion:

In summary, while all three articles provide valuable insights into the management of AF and the role of catheter ablation, they each have unique perspectives and areas of emphasis. Combining the recommendations and findings from these articles can help healthcare providers develop comprehensive and individualized treatment plans for their patients with AF.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none"> ● Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices ● Added other indications of atrial fibrillation ablation and updated treatment for early recurrence after catheter ablation ● Adjusted applicable lines of business – Medicare Advantage checked ● Updated references ● Added a Summary of Evidence and Analysis of Evidence

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM Cardio 1141 Cardio Policy EPS with AI, Pacing after DI and Atrial or SVT and AP Ablation • This guideline replaces UM Cardio 1142 Cardio Policy EPS with AI for AFib AVN and AP Ablation

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7283 for Abdominal Aortography with Bilateral Iliofemoral Lower Extremity Runoff

Guideline Number: Evolent_CG_7283	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: July 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Abdominal Aortography with Bilateral Iliofemoral Lower Extremity Runoff.

Special Note

Decisions regarding the potential utility of invasive therapeutic interventions (percutaneous or surgical) in patients with lower extremity peripheral arterial disease should be made with a complete anatomic assessment of the affected arterial territory, including imaging of the occlusive lesion, as well as arterial inflow and outflow with angiography or a combination of angiography and noninvasive vascular techniques.

Noninvasive imaging modalities, including MRA, CTA, and color flow duplex imaging, may be used in advance of invasive imaging to develop an individualized diagnostic strategic plan, including assistance in selection of access sites, identification of significant lesions, and determination of the need for invasive evaluation.

Diagnostic peripheral angiography performed at the time of an interventional procedure is separately reportable if at least one indication for medical necessity for a stand-alone lower extremity is met AND one of the following is also met:

- No prior catheter-based angiographic study is available, and a full diagnostic study is performed, and the decision to intervene is based on the diagnostic study, or
- A prior study is available, but as documented in the medical record:
 - the patient's condition with respect to the clinical indication has changed since the prior study; or
 - there is inadequate visualization of the anatomy or pathology; or
 - there is a clinical change during the interventional procedure that requires new

evaluation outside the target area of intervention.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS ^(6,7)

- Significant disability with documentation of outflow or inflow peripheral arterial disease by prior non-invasive study and further study is needed by angiography with the intent of subsequent intervention
- Following:
 - detection of aneurysm and other primary vascular abnormalities that require further investigation for effective treatment
 - the detection of occlusive disease, including evaluation for acute or chronic intestinal ischemia
 - stabilization of GI hemorrhage as an outpatient/elective procedure

CODING AND STANDARDS

Codes

36200, 36245, 36246, 36247, 36248, 75625, 75630, 75710, 75716, 75726, G0278

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace

<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

SUMMARY OF EVIDENCE

ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention⁽⁷⁾

Study Design: This study involved the development of Appropriate Use Criteria (AUC) for peripheral artery intervention (PAI). The process included drafting patient scenarios, assumptions, and definitions based on published guidelines, trial data, and expert opinions. The scenarios were evaluated by an independent rating panel using a scoring scale from 1 to 9.

Target Population: The study focused on patients with peripheral artery disease (PAD) who may require revascularization treatments. This includes patients with renal artery stenosis, lower extremity disease, critical limb ischemia, asymptomatic artery disease, and secondary treatment options for lower extremity disease.

Key Factors:

Clinical Scenarios: 45 clinical scenarios with up to 6 intervention options per scenario were developed and categorized into 6 general sections.

Scoring: Each indication was scored as “Appropriate” (7 to 9), “May Be Appropriate” (4 to 6), or “Rarely Appropriate” (1 to 3).

Emphasis: Adherence to medical therapy was emphasized, with revascularization considered when medical therapy is insufficient.

Endovascular and Surgical Approaches: Both approaches were deemed appropriate in scenarios involving tissue loss or end organ compromise, with a tendency to select endovascular approaches.

2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease ⁽⁶⁾

Study Design: This guideline was developed by the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. It involved a systematic review of literature, including randomized controlled trials, registries, nonrandomized comparative and descriptive studies, case series, cohort studies, systematic reviews, and expert opinion.

Target Population: The guideline focuses on patients with lower extremity peripheral artery disease (PAD), including those with claudication, critical limb ischemia, acute limb ischemia, and other related conditions.

Key Factors:

Recommendations: The guideline provides evidence-based recommendations for the diagnosis and management of PAD, including medical therapy, structured exercise, revascularization, and wound healing therapies.

Diagnostic Testing: Resting ABI, exercise treadmill ABI, TBI, TcPO₂, and SPP are recommended for diagnosing PAD and assessing perfusion.

Medical Therapy: Antiplatelet agents, statins, antihypertensive agents, smoking cessation, glycemic control, and other therapies are recommended to reduce cardiovascular events and improve limb outcomes.

Structured Exercise: Supervised exercise programs are recommended to improve functional status and quality of life.

Revascularization: Endovascular and surgical revascularization are recommended for patients with lifestyle-limiting claudication and critical limb ischemia.

Wound Healing: Comprehensive care by an interdisciplinary team is recommended to achieve complete wound healing and preserve a functional foot.

ANALYSIS OF EVIDENCE

Shared Findings ^(6,7)

Both articles emphasize the importance of accurate diagnosis and management of peripheral artery disease (PAD) and highlight the role of abdominal aortography in assessing vascular conditions.

Clinical Benefits

- **Diagnosis and Management:** Both studies underscore the significance of abdominal aortography in diagnosing and managing PAD. Gerhard-Herman et al. (2016) discuss the comprehensive guidelines for the management of lower extremity PAD, including the use of imaging techniques like abdominal aortography. Similarly, Bailey et al. (2019) highlight the appropriate use criteria for peripheral artery interventions, including abdominal aortography.
- **Assessment of Vascular Conditions:** Both articles agree on the utility of abdominal aortography in assessing vascular conditions, particularly in patients with symptomatic

PAD. Gerhard-Herman et al. (2016) mention the importance of imaging for anatomic assessment in patients with PAD¹. Bailey et al. (2019) also emphasize the role of imaging in evaluating the severity of stenosis and planning revascularization.

Safety Profile

- **Safety and Efficacy:** Both articles confirm the safety and efficacy of abdominal aortography. Gerhard-Herman et al. (2016) report that imaging techniques like abdominal aortography are useful for diagnosing anatomic location and severity of stenosis¹. Bailey et al. (2019) also highlight the importance of imaging in ensuring accurate diagnosis and effective treatment planning.

Both articles provide strong evidence supporting the use of abdominal aortography in the diagnosis and management of PAD, particularly in assessing vascular conditions and planning revascularization. Gerhard-Herman et al. (2016) offer comprehensive guidelines for the management of lower extremity PAD, while Bailey et al. (2019) provide specific recommendations and cost-effectiveness analysis for peripheral artery interventions. Together, these findings underscore the potential of abdominal aortography to enhance PAD management and patient outcomes.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none">● Added Summary of Evidence and Analysis of Evidence
June 2025	<ul style="list-style-type: none">● Removed GDMT requirement● Added third bullet to General Information
January 2025	<ul style="list-style-type: none">● This guideline replaces UM 1170 Abdominal Aortography with Bilateral Iliofemoral Lower Extremity Runoff

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guideline 7284 for Catheter Ablation of Reentrant or Focal Tachydysrhythmias

Guideline Number: Evolent_CG_7284	<u>Applicable Codes</u>	
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Original Date: January 2025	Last Revised Date: July 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations*

Purpose

To identify the indications for catheter ablation of focal or reentrant cardiac tachydysrhythmias.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR CATHETER ABLATION OF CARDIAC ARRHYTHMIAS

Supraventricular Tachycardias ^(6,7)

Ablation of Supraventricular Tachycardias

Patients with any of the following:

- Frequent or poorly tolerated episodes of sustained tachycardia that do not adequately respond to drug therapy

- Who prefer ablative therapy compared to pharmacological treatment
- Frequent episodes of tachycardia requiring drug treatment when there is concern about side effects of the antiarrhythmic drug

Supraventricular Tachycardia Amenable to Ablation

- Inappropriate Sinus Tachycardia: Sinus node modification should be considered only for patients who are highly symptomatic and cannot be adequately treated by medication, and then only with documentation of informing the patient that the risks may outweigh the benefits.
- Focal Atrial Tachycardia (AT): patients with symptomatic focal AT as an alternative to pharmacological therapy
- Patients with Atrioventricular Nodal Reentrant Tachycardia (AVNRT— the most common form of SVT)
- Manifest and Concealed Accessory Pathways (Wolff-Parkinson-White WPW with or without atrioventricular reentrant tachycardia (AVRT)), catheter ablation of accessory pathway for any of the following:
 - AVRT and/or pre-excited atrial fibrillation
 - Electrophysiology study (EPS) demonstrates a high risk of dangerous events, including rapidly conducting pre-excited atrial fibrillation (shortest R-R interval ≤ 250 msec)
 - Asymptomatic persons with high-risk occupations (airline pilots, police, firefighters, etc.)
- Atrial Flutter:
 - Catheter ablation of cavo-tricuspid-dependent (typical type 1 or 2) atrial flutter is recommended as an alternative to pharmacological therapy for symptomatic patients
 - For asymptomatic patients when drug therapy fails to achieve adequate rate control
 - Catheter ablation of non-cavo-tricuspid-dependent (atypical and left sided) atrial flutter is recommended for symptomatic recurrent flutter after failure of at least one antiarrhythmic drug. It may be performed in patients who prefer ablation therapy over pharmacological treatment after thorough discussion of the risks and complexity of ablation.
- Junctional Tachycardia:
 - Catheter ablation of accelerated junctional rhythm may be performed in symptomatic patients who have failed medical therapy with beta blockers, calcium channel blockers, or Class IC drugs, or when medical therapy is contraindicated

Catheter Ablation in Pediatric Patients: Elective catheter ablation is reserved for patients > 15 kg. Ablation of SVT in smaller patients (< 15 kg) should be reserved for arrhythmias refractory to drug therapy or resulting in tachycardia-related cardiomyopathy.

Ventricular Arrhythmias (6,8,9)

Ventricular Extrasystoles

- Isolated frequent monomorphic premature ventricular contractions (PVCs) resulting in tachycardia-associated cardiomyopathy (Left ventricular ejection fraction LVEF < 50%) are an indication for mapping and ablation of the source of the extrasystoles
- PVC ablation may be performed in patients with **highly symptomatic**, monomorphic PVCs, couplets, or non-sustained ventricular tachycardia (NSVT), independent of ejection fraction
- Mapping and ablation of frequent monomorphic ventricular extrasystoles may be performed in patients with other risk factors for future arrhythmic events, such as:
 - Positive signal-averaged electrocardiogram (ECG)
 - Nonsustained VT on ambulatory ECG recordings with inducible sustained monomorphic ventricular tachycardia on EPS

NOTE: Catheter ablation is **NOT** indicated for asymptomatic patients with PVCs, couplets, and nonsustained VT without other risk factors for sustained arrhythmias.

Ventricular Tachycardia without Apparent Structural Heart Disease

- In patients with symptomatic outflow tract ventricular tachycardias in an otherwise normal heart for whom antiarrhythmic medications are ineffective, not tolerated, or not the patient's preference
- Catheter ablation of fascicular ventricular tachycardia is indicated for patients with symptomatic ventricular tachycardia (VT) when refractory to medical therapy or when the patient prefers catheter ablation over medical therapy
- Catheter ablation may be performed in patients with symptomatic papillary muscle ventricular tachycardia for whom antiarrhythmic medications are ineffective, not tolerated, or not the patient's preference

Ventricular Tachycardia with Structural Heart Disease

- In patients with ischemic heart disease and recurrent ventricular tachycardia with an implantable cardioverter-defibrillator (ICD) in place, catheter ablation may be performed after failure of antiarrhythmic therapy (i.e., treatment with amiodarone or sotalol should be utilized to suppress recurrent VT prior to consideration of catheter ablation)
- With prior myocardial infarction and ICD shocks for sustained monomorphic VT or symptomatic sustained monomorphic VT that is recurrent and hemodynamically tolerated, catheter ablation as first-line therapy may be performed to reduce recurrent ventricular tachycardia
- Nonischemic cardiomyopathy and recurrent sustained monomorphic VT with failure or intolerance of antiarrhythmic medications, catheter ablation may be performed for reducing recurrent VT and ICD shocks
- In bundle branch reentrant ventricular tachycardia, catheter ablation may be performed

for reducing the risk of recurrent VT

Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC)

- Ablation is appropriate for:
 - Arrhythmogenic right ventricular cardiomyopathy (ARVC) patients who have experienced recurrent VT or ICD therapies (shocks or antitachycardia pacing), refractory to antiarrhythmic therapy
 - ARVC that has failed one or more attempts at catheter ablation of recurrent ventricular tachycardia, ablation using an epicardial approach is recommended
 - ARVC patients with recurrent VT that is symptomatic or requires ICD therapy who prefer not to use antiarrhythmic drugs

CODING AND STANDARDS

Codes

93462, 93654

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

With the exception of incessant rhythm disturbances and atrial fibrillation, most ablation procedures will be performed after (frequently immediately after) electrophysiology studies in which the mechanism of the dysrhythmia will have been elucidated. ⁽⁶⁾

Ablation of cardiac arrhythmias involves the use of multielectrode catheters introduced into the cardiac chambers, and typically positioned in the right atrium, right ventricle, region of the A-V Node and/or the Bundle of His, and frequently the coronary sinus. Several access sites are typically required, and may include the femoral vein(s), jugular vein(s), subclavian vein(s) and the brachial vein(s). When access to the left heart is required, an atrial transseptal puncture may be utilized, or a retrograde approach via the femoral artery and across the aortic valve; systemic

anticoagulation is mandated in these cases. Sophisticated mapping systems are often utilized in ablation procedures to generate 3-dimensional representations of the cardiac chambers, characterizing the sequence of activation of myocardium during arrhythmia, the presence of scar tissue and areas of slow conduction of electrical impulses, and anatomic barriers that serve as targets to modify the substrate and eliminate or reduce arrhythmia recurrence. ⁽¹⁰⁾

Radiofrequency current is the most used energy source for ablation. Cryoablation is a useful alternative to radiofrequency ablation. Cryoablation has been shown to minimize injury to the AV node during ablation of specific arrhythmias, such as AVNRT, para-Hisian atrial tachycardia, and para-Hisian accessory pathways, especially in children and young adults. Selection of the energy source depends on operator experience, arrhythmia target location, and patient preference. Catheter ablation is typically performed using an endocardial approach. In selected cases, particularly in ventricular tachycardias in patients with nonischemic cardiomyopathy, an epicardial approach accessing the pericardial space, may be required to reach target sites for ablation. ⁽⁷⁻⁹⁾

Typical counterclockwise atrial flutter depends on a large reentrant circuit with a region of slow conduction in the cavo-tricuspid isthmus and has a characteristic appearance of the P waves on 12 lead ECG. Non-cavo-tricuspid isthmus-dependent flutters are generated by atrial scarring, which may develop after prior ablation procedures in the atrium (such as atrial fibrillation ablation), and after surgical interventions involving atriotomy. They require more extensive and complex mapping than typical atrial flutter. ⁽⁷⁾

Paroxysmal junctional tachycardia (aka junctional ectopic tachycardia is rare in adults) is seen most commonly in pediatric postoperative patients and after surgery for congenital heart disease in adults. Nonparoxysmal junctional tachycardia (aka accelerated junctional rhythm) is more common, typically benign, and usually responds well to pharmacological therapy. It is sometimes seen after slow pathway ablation for AVNRT and is usually self-limited. ⁽⁷⁾

Idiopathic monomorphic ventricular tachycardias in patients with structurally normal hearts are commonly the result of triggered activity or abnormal automaticity, while a few involve microreentry. They have a more benign clinical course than VT seen in association with structural heart disease, and often respond to calcium channel blockers and Type Ic antiarrhythmic drugs. Catheter ablation is appropriate for symptomatic patients who are either refractory to medical therapy or who prefer catheter ablation over medical treatment. ^(8,9)

Sustained ventricular tachycardia in patients with structural heart disease is usually treated with implantation of an ICD. Ablation is reserved for patients with frequent episodes of symptomatic VT that is refractory to therapy with antiarrhythmic drugs or in whom pharmacological therapy is not tolerated or contraindicated. Some patients have sustained VT which is hemodynamically well-tolerated, but often recurrent or incessant. In these cases, catheter ablation is recommended and often effective. ⁽⁸⁾

Bellhausen's idiopathic left ventricular tachycardia (fascicular VT) is caused by reentry involving a portion of the left ventricular Purkinje system, usually the left posterior fascicle as the retrograde limb of the circuit and a poorly defined segment of LV tissue as the anterograde limb. Parts of the circuit are often verapamil-sensitive. These VTs demonstrate a right bundle-branch block configuration with a superior axis and are amenable to catheter ablation with high rates of success. ^(8,9)

Bundle branch reentrant ventricular tachycardia is normally seen in patients with advanced left ventricular cardiomyopathy. The reentrant circuit incorporates the right bundle branch for

anterograde conduction and the left bundle as the retrograde limb. Rates are usually more than 200 bpm and are poorly tolerated hemodynamically. Ablation of the right bundle branch can be curative. ⁽⁹⁾

Definitions

- Frequent ventricular extrasystoles: >30 PVCs per hour on Holter or other extended monitoring system
- Monomorphic ventricular extrasystoles: PVCs with a single, identical morphology in all the leads recorded on an ECG or heart monitor
- Sustained tachycardia: tachycardias lasting 20 seconds or longer, or requiring cardioversion because of hemodynamic collapse or compromise

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ARVC: arrhythmogenic right ventricular cardiomyopathy

AT: atrial tachycardia

AUC: appropriate use criteria

AV: atrioventricular

AVNRT: atrioventricular nodal reentrant tachycardia

AVRT: atrioventricular reentrant tachycardia

ECG: electrocardiogram

EPS: electrophysiology study

ICD: implantable cardioverter-defibrillator

kg: kilogram

LVEF: left ventricular ejection fraction

NSVT: non-sustained ventricular tachycardia

PVC: premature ventricular contractions

SVT: supraventricular tachycardia

VT: ventricular tachycardia

WPW: Wolff-Parkinson-White syndrome

SUMMARY OF EVIDENCE

2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death ⁽⁸⁾

Study Design: This document is a clinical practice guideline developed by the American College of Cardiology, American Heart Association, and Heart Rhythm Society. It is based on a systematic review of the literature and expert consensus.

Target Population: The guidelines are intended for patients with ventricular arrhythmias and those at risk of sudden cardiac death.

Key Factors: The document covers a wide range of topics, including the epidemiology of ventricular arrhythmias, mechanisms of arrhythmias, general evaluation of patients, and various therapies for treatment or prevention. It also discusses specific disease states and populations, such as athletes, pregnant women, and older patients.

Recommendations for the use of electrophysiological study: Update 2018 ⁽⁶⁾

Study Design: This is a review article that provides updated recommendations for the use of electrophysiological studies (EPS) in clinical practice. The recommendations are based on a comprehensive review of the literature and clinical guidelines from various cardiology societies.

Target Population: The recommendations apply to patients with different types of cardiac pathologies, including sinus node dysfunction, atrioventricular block, bundle branch block, and various types of tachycardias.

Key Factors: The document discusses the role of EPS in diagnosing and managing various cardiac conditions, the indications for EPS, and the evidence supporting its use. It also provides specific recommendations for different cardiac diseases and patient populations.

2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia ⁽⁷⁾

Study Design: This document is a clinical practice guideline for the management of adult patients with supraventricular tachycardia (SVT). It is developed by the American College of Cardiology, American Heart Association, and Heart Rhythm Society, based on a systematic review of the literature.

Target Population: The guidelines are intended for adult patients with SVT, excluding atrial fibrillation.

Key Factors: The document covers the mechanisms and definitions of SVT, epidemiology, clinical evaluation, and principles of medical therapy. It also provides detailed recommendations for the acute and ongoing management of various types of SVT, including focal atrial tachycardia, atrioventricular nodal reentrant tachycardia, and atrial flutter.

ANALYSIS OF EVIDENCE

Shared Conclusions:

- Effectiveness: All three documents agree on the effectiveness of catheter ablation in treating various types of cardiac arrhythmias, including ventricular arrhythmias, SVT, and atrial flutter.
- Patient Selection: They emphasize the importance of careful patient selection to ensure successful outcomes and minimize complications.
- Expertise: High expertise and experience in performing catheter ablation are crucial for achieving optimal results.

Conclusion:

In summary, while all three documents support the use of catheter ablation for treating cardiac arrhythmias, they differ in their focus on specific conditions, the prognostic value of EPS, and considerations for specific populations.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none">● Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices● No significant clinical changes● Added a Summary of Evidence and Analysis of Evidence
December 2024	<ul style="list-style-type: none">● This guideline replaces UM Cardio 1140 Cardio Policy EPS with Transseptal Left Heart Cath with Arrhythmia Induction and VT Ablation

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7285 for Abdominal Aortic Aneurysm Repair

Guideline Number: Evolent_CG_7285	<u>Applicable Codes</u>	
<i>"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc.</i> <i>© 2011 - 2026 Evolent. All rights Reserved.</i>		
Original Date: September 2011	Last Revised Date: May 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for repair of an abdominal aortic or iliac artery aneurysm.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS

The choice of endovascular or open surgical repair for elective treatment of abdominal aortic aneurysm (AAA) or iliac artery aneurysm (IAA) should be individualized with appropriate consideration of the following ⁽⁶⁾:

- Anatomic suitability for endovascular aneurysm repair (EVAR)
- Comorbidities and physical fitness
- Life expectancy

- Compliance with postoperative surveillance
- Patient preference

Abdominal Aortic Aneurysm

Repair is indicated for **ANY** of the following ^(6–8):

- Ruptured AAA
- AAA when maximal aneurysm diameter as measured by CTA (unless contraindicated) is ≥ 5.5 cm in men or ≥ 5.0 cm in women
- AAA growth rate of ≥ 0.5 cm in 6 months
- In patients with back or abdominal pain that can be attributed to the AAA
- Saccular AAA
- Inflammatory AAA
- Mycotic AAA
- Perianastomotic graft aneurysm
- Pseudoaneurysm or complicated penetrating aortic ulcer (PAU), isolated dissection, or intramural hematoma (IM) with ANY of the following:
 - Expansion
 - Co-existing peri-aortic or extra-aortic hematoma
 - Embolization
 - Recurrent pain
 - Malperfusion

Iliac Aneurysm

Includes: common iliac, internal iliac, external iliac, or any combination thereof as measured by CTA (unless contraindicated). Repair is indicated for **ANY** of the following ⁽⁸⁾:

- Aneurysm ≥ 40 mm
 - Repair of an aneurysm ≥ 35 mm in a female patient may be reasonable due to sex differences in normal artery size
- Aneurysms < 40 mm in conjunction with repair of an AAA

Endoleak

Endovascular treatment should be the first line treatment for endoleak. Open surgery should be utilized when endovascular procedures have been unsuccessful. Examples of endoleak that indicate repair include ⁽⁹⁾:

- Type I endoleak

- Type II endoleak with evidence of expansion
- Type III endoleak
- Unexplained aneurysm expansion following graft

Other Considerations

- Elective repair of AAA, by either endovascular or open surgical procedures, is not recommended in patients with a limited life expectancy (<2-3 years) ⁽⁸⁾
- Open surgical repair of AAA is preferred over endovascular procedures in patients with long life expectancies (>10-15 years) ⁽⁸⁾

Limitations

- When commercially available grafts are used for endovascular repair of aortic aneurysms, implantation must follow the device's specific instructions for use (IFU)
- Approval for outpatient treatment does not extend to outpatient endovascular repair of AAA

CODING AND STANDARDS

Codes

34701, 34702, 34703, 34704, 34705, 34706, 34707, 34708, 34709, 34710, 34711, 34712, 34713, 34714, 34715, 34716, 34717, 34718, 34808, 34812, 34813, 34820, 34833, 34834, 34841, 34842, 34843, 34844, 34845, 34846, 34847, 34848, 35081, 35082, 35091, 35092, 35102, 35103, 35131, 35132

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- An **aneurysm** is a ballooning of all the walls of the artery and occurs when the artery increases in size by 1.5 of its original size.
- **Pseudoaneurysm** involves blood outside the wall of the aneurysm but contained by surrounding structures.
- **Saccular aneurysm** is a ballooning of part of the wall of an artery. It accrues a greater risk of rupture.
- **Endovascular AAA** repair involves the placement of a stent graft within the affected blood vessel through an artery (usually the femoral artery), and which seals the aneurysm sac from within.
- **Endoleak** implies continuous filling of the aneurysm sac despite prior endograft. It is classified as Type I-IV depending on from where the endoleak arises.
- **Open Surgery** is used to sew in an aortic graft. It can be performed via a midline or retroperitoneal approach.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AAA: Abdominal aortic aneurysm

AUC: Appropriate use criteria

CTA: Computed tomographic Angiography

IFU: Instructions for use

IH: Intramural hematoma

IRB: Institutional Review Board

PAU: Penetrating aortic ulcer

TAAA: Thoracoabdominal aortic aneurysm

SUMMARY OF EVIDENCE

Society for Vascular Surgery implementation of clinical practice guidelines for patients with an abdominal aortic aneurysm: Repair of an abdominal aortic aneurysm ⁽⁶⁾

Study Design: This document outlines the Society for Vascular Surgery's clinical practice guidelines for the repair of abdominal aortic aneurysms (AAA). The guidelines are based on a comprehensive review of observational studies and randomized controlled trials (RCTs) to determine the optimal timing and method of AAA repair.

Target Population: The guidelines are intended for patients with AAA, including those with ruptured, symptomatic non-ruptured, and asymptomatic aneurysms. The recommendations are aimed at vascular surgeons, interventional radiologists, and other healthcare professionals involved in the management of AAA.

Key Factors:

Timing of Repair: Emergent repair is recommended for ruptured AAAs, urgent treatment for symptomatic non-ruptured aneurysms, and elective repair for asymptomatic AAAs after preoperative assessment.

Surgical Approach: Endovascular aneurysm repair (EVAR) is recommended for ruptured AAAs if anatomically feasible, with a suggested door-to-intervention time of less than 90 minutes. Open surgical repair (OSR) is considered for elective treatment when EVAR is not suitable.

Risk Assessment: The guidelines emphasize the importance of using risk assessment tools to predict treatment outcomes and inform patient-centered communication and decision-making.

Implementation Strategy: The implementation of structured, multidisciplinary triage protocols for the emergent management of ruptured AAAs is associated with a significant decrease in 30-day mortality.

2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines ⁽⁷⁾

Study Design: The guidelines were developed by the American Heart Association (AHA) and the American College of Cardiology (ACC) Joint Committee on Clinical Practice Guidelines. The recommendations are based on a comprehensive literature search conducted from January 2021 to April 2021, encompassing studies, reviews, and other evidence conducted on human subjects published in English from PubMed, EMBASE, the Cochrane Library, CINHL Complete, and other selected databases relevant to this guideline. Additional relevant studies published through June 2022 were also considered by the writing committee.

Target Population: The guidelines are intended for clinicians involved in the diagnosis, genetic evaluation, family screening, medical therapy, endovascular and surgical treatment, and long-term surveillance of patients with aortic disease across its multiple clinical presentation subsets (i.e., asymptomatic, stable symptomatic, and acute aortic syndromes). The recommendations apply to patients with or at risk of developing cardiovascular disease, with a focus on medical practice in the United States but relevant to patients worldwide.

Key Factors:

Recommendations: The guidelines update previously published AHA/ACC guidelines on thoracic aortic disease, peripheral artery disease, and bicuspid aortic valve disease with new evidence. New recommendations addressing comprehensive care for patients with aortic disease have been developed, emphasizing shared decision-making and the importance of institutional interventional volume and multidisciplinary aortic team expertise.

Imaging Techniques: The guidelines provide detailed recommendations on aortic imaging techniques, including computed tomography (CT), magnetic resonance imaging (MRI), echocardiography, and ultrasound, to determine the presence and progression of aortic disease.

Surgical and Endovascular Management: The guidelines discuss the timing and types of surgical and endovascular interventions for aortic aneurysms, acute aortic syndromes, and other aortic conditions. They emphasize the importance of multidisciplinary aortic teams and high-volume centers for optimizing treatment outcomes.

Medical Management: The guidelines include recommendations for medical therapy, including antihypertensive medications, statins, smoking cessation, and antiplatelet therapy, to manage aortic disease and reduce the risk of adverse aortic events.

Surveillance: The guidelines provide recommendations for surveillance imaging after aortic repair to monitor for complications and progression of residual aortic pathology.

Editor's Choice – European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the management of Abdominal Aorto-Iliac Artery Aneurysms ⁽⁸⁾

Study Design: This document presents the European Society for Vascular Surgery (ESVS) 2024 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. The guidelines are based on a combination of scientific evidence and expert opinion, with recommendations graded according to a modified European Society of Cardiology grading system.

Target Population: The guidelines are intended for physicians and healthcare professionals involved in the management of patients with aneurysms of the abdominal aorta and iliac arteries. This includes vascular surgeons, interventional radiologists, and other specialists.

Key Factors:

Service Standards: The guidelines emphasize the importance of quality control, surgical volume, and training in aortic surgery. They recommend that centers performing aortic surgery participate in validated prospective registries to monitor practice and outcomes.

Epidemiology, Diagnosis, and Screening: The guidelines provide recommendations for the diagnosis and screening of AAAs, including the use of ultrasonography and computed tomography angiography (CTA) for treatment planning.

Management of Small AAAs: The guidelines outline surveillance intervals for small AAAs and recommend cardiovascular risk factor management, including smoking cessation, blood pressure control, and statin and antiplatelet therapy.

Elective AAA Repair: The guidelines provide detailed recommendations for the pre-operative management, including risk assessment and optimization, and the choice of surgical technique (open or endovascular repair).

Ruptured and Symptomatic AAAs: The guidelines discuss the peri-operative management of ruptured and symptomatic AAAs, including the use of permissive hypotension and aortic occlusion balloons.

Long-term Follow-up: The guidelines emphasize the importance of long-term follow-up after AAA repair to detect late complications and ensure the durability of the repair. These guidelines provide comprehensive, up-to-date recommendations for the management of abdominal aorto-iliac artery aneurysms, aiming to assist healthcare professionals in selecting the best management strategies for their patients.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(6–8)

1. Indications for Surgery:

- All three articles agree that AAA repair is indicated for patients with symptomatic or ruptured AAA. They also concur that elective repair should be considered for asymptomatic AAA when the aneurysm reaches a certain diameter threshold.

2. Surgical Techniques:

- **Endovascular Aneurysm Repair (EVAR)** is preferred over **Open Surgical Repair (OSR)** when anatomically feasible, as it is associated with lower perioperative mortality and faster recovery. However, OSR is recommended when the aortic anatomy does not meet the criteria for EVAR.

3. Preoperative Assessment:

- Comprehensive preoperative assessment including imaging techniques like CT and MRI is emphasized to evaluate the aneurysm and plan the intervention.

Summary ^(6–8)

The three articles provide a comprehensive overview of AAA repair, with shared conclusions on indications for surgery, surgical techniques, and preoperative assessment.

POLICY HISTORY

Date	Summary
May 2025	<ul style="list-style-type: none"> ● Edited text for clarity ● Added third General Information bullet ● Added Summary of Evidence and Analysis of Evidence
January 2025	<ul style="list-style-type: none"> ● This guideline merges, and replaces, UM CARDIO_1162 for Endovascular Aortic and Iliac Artery Aneurysm Repair and UM CARDIO_1337 for Abdominal Aorta and Iliac Aneurysm Open

Date	Summary
	<p>Repair</p> <ul style="list-style-type: none"> • Indications, CPT codes, and Applicable Lines of Business were merged and reconciled • Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolut Clinical Guideline 7286 for Endomyocardial Biopsy

Guideline Number: Evolut_CG_7286	<u>Applicable Codes</u>	
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Original Date: February 2020	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for endomyocardial biopsy.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS

Heart Transplant (HT) Recipients ⁽⁶⁾

Patients with no evidence of rejection:

Endomyocardial biopsy (EMB) may be used for routine monitoring of heart transplant patients on the following schedule:

- Periodically during the first 3-12 months postoperatively
- For continued surveillance of patients at high risk for rejection 1-5 years postoperatively

- Surveillance EMB > 5 years after HT at the discretion of the transplant service

Patients with known or suspected rejection:

- Signs and symptoms of acute rejection including:
 - Sustained ventricular tachycardia
 - New onset atrial arrhythmia
 - New onset ventricular arrhythmia
 - Aborted sudden death
- 2-4 weeks after initiation of treatment for acute cellular rejection
- Surveillance of untreated asymptomatic moderate cellular rejection
- 1-4 weeks after initiation of treatment for antibody mediated rejection

Suspected Myocarditis (7–9)

EMB may be appropriate in patients for whom a histological diagnosis may inform treatment in the following circumstances:

- Suspected fulminant myocarditis. Signs may include:
 - Unexplained acute heart failure (HF) and left ventricular (LV) dysfunction
 - Cardiogenic shock or hemodynamic instability
 - Ventricular arrhythmias and/or second- or third-degree heart block
- Hemodynamically stable patients with suspected myocarditis based upon new onset HF and associated signs of myocarditis such as ECG abnormalities and elevated biomarkers (i.e. troponin) in the absence of coronary artery disease

Cardiomyopathy/Heart Failure (8–12)

EMB may be appropriate in patients for whom a histological diagnosis may inform treatment in the following circumstances:

- Recent onset heart failure with dilated cardiomyopathy and moderate to severe LV dysfunction, refractory to standard therapy and after exclusion of specific etiologies.
- Second- or third-degree heart block, syncope and/or unexplained ventricular arrhythmias refractory to therapy without obvious cardiac abnormalities or with minimal cardiac structural abnormalities (possible sarcoidosis, arrhythmogenic right ventricular dysplasia (ARVD), etc.)
- Dilated cardiomyopathy of any duration with suspected hypersensitivity (i.e. allergic) reaction and/or eosinophilia
- Suspected immune checkpoint inhibitor (ICI)-mediated toxicity (i.e., acute HF early after drug initiation)
- HF associated with suspected anthracycline cardiomyopathy

- HF associated with unexplained restrictive or hypertrophic cardiomyopathy (possible amyloidosis or other infiltrative/depositional/storage disorder)
- Autoimmune disorders with worsening HF unresponsive to therapy
- Suspected idiopathic inflammatory myopathy (IIM) with cardiac involvement
- Cardiac tumors
- Unexplained cardiomyopathy in children
- Heart transplant candidates suspected of having an infiltrative or inflammatory cardiomyopathy

CODING AND STANDARDS

Codes

76932, 93505

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ARVD: Arrhythmogenic right ventricular dysplasia

EMB: Endomyocardial biopsy

HF: Heart failure

HT: Heart transplant

ICI: Immune checkpoint inhibitor

IIM: Idiopathic inflammatory myopathy

LV: Left ventricle

SUMMARY OF EVIDENCE

The International Society for Heart and Lung Transplantation (ISHLT) guidelines for the care of heart transplant recipients ⁽⁶⁾

Study Design: The guidelines were developed through a focused update to the original practice guidelines published in 2010. The update involved a vast effort by 39 writers from 11 countries worldwide, organized into four Task Force groups. Each group was co-chaired by a pediatric heart transplant clinician to ensure adequate representation of issues unique to the pediatric heart transplant population. The guidelines were endorsed by the Pediatric Heart Transplant Society and reviewed by independent experts.

Target Population: The guidelines are intended for heart transplant recipients, including both adult and pediatric populations. Specific considerations are given to pediatric recipients, particularly those under 2 years of age, and patients with unique conditions such as congenital heart disease, sensitization, and those requiring mechanical circulatory support.

Key Factors

Perioperative Care: This includes pre-transplant optimization, surgical issues impacting immediate post-operative care, and management of patients bridged with mechanical circulatory support.

Immunosuppression and Rejection: The guidelines cover rejection surveillance, monitoring of immunosuppressive drug levels, principles of immunosuppression, and treatment of acute cellular and antibody-mediated rejection.

Long-term Care: This involves management of complications such as chronic kidney disease, malignancy, cardiac allograft vasculopathy, and neurologic complications. It also includes recommendations for minimizing immunosuppression and managing cardiovascular risk factors.

Special Populations: Specific guidelines are provided for pediatric recipients, including those undergoing ABO-incompatible transplants and those with congenital heart disease.

Emerging Therapies: The guidelines discuss the use of newer immunosuppressive agents and techniques, such as belatacept and tocilizumab, and the role of extended-release formulations of tacrolimus.

Heart Failure Association of the ESC, Heart Failure Society of America and Japanese Heart Failure Society Position statement on endomyocardial biopsy ⁽⁹⁾

Study Design: The document is a result of the Trilateral Cooperation Project between the Heart Failure Association of the European Society of Cardiology, the Heart Failure Society of America, and the Japanese Heart Failure Society. It represents an expert consensus aiming to provide a comprehensive, up-to-date perspective on EMB.

Target Population: The target population includes patients undergoing heart transplant (HTx) and those with diverse cardiac disorders such as myocarditis, cardiomyopathies, drug-related cardiotoxicity, amyloidosis, other infiltrative and storage disorders, and cardiac tumors.

Key Factors:

Overview of Practical Approach to EMB: The document provides an overview of the practical approach to EMB, including the selection of the access site, patient monitoring, and the number of EMBs per operator required to maintain procedural skill.

Indications for EMB: It updates the indications for EMB, including its role in diagnosing various cardiac disorders and monitoring HTx rejection.

Impact of Multimodality Imaging on EMB: The document discusses the impact of multimodality imaging on EMB, highlighting the role of imaging in guiding EMB and improving diagnostic accuracy.

Current Clinical Practice: It provides insights into the current clinical practice of EMB worldwide, including the variability in its use across different countries.

2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure ⁽¹⁰⁾

Study Design: This document is a clinical practice guideline by the American College of Cardiology/American Heart Association/Heart Failure Society of America (ACC/AHA/HFSA) for the management of heart failure. It includes recommendations based on systematic literature reviews and expert consensus.

Target Population: Patients with heart failure, including those with reduced ejection fraction (HFrEF), preserved ejection fraction (HFpEF), mildly reduced ejection fraction (HFmrEF), and improved ejection fraction (HFimpEF).

Key Factors:

Epidemiology: The document provides data on the prevalence of heart failure and discusses risk factors such as hypertension, diabetes, obesity, and atherosclerotic cardiovascular disease.

Stages of Heart Failure: It outlines the ACC/AHA stages of heart failure, emphasizing the development and progression of the disease.

Diagnostic Algorithm: Recommendations for the classification of heart failure based on left ventricular ejection fraction (LVEF) and diagnostic criteria.

Management: Guidelines for the use of guideline-directed medical therapy (GDMT), including ACE inhibitors, ARBs, ARNIs, beta blockers, MRAs, and SGLT2 inhibitors. Recommendations for nonpharmacological interventions such as exercise training, cardiac rehabilitation, and dietary sodium restriction.

Special Populations: Management strategies for patients with comorbidities, including atrial fibrillation, coronary artery disease, and diabetes.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(6,9,10)

1. **Heart Failure Management:** All three articles emphasize the importance of managing heart failure (HF) through various strategies. They discuss the use of medications, lifestyle changes, and monitoring techniques to improve patient outcomes and reduce hospitalizations.
2. **Role of Biomarkers:** The articles highlight the significance of biomarkers such as B-type natriuretic peptide (BNP) and N-terminal prohormone of B-type natriuretic peptide (NT-proBNP) in diagnosing and managing HF. These biomarkers are useful for risk stratification and guiding treatment decisions.

Importance of Multidisciplinary Care: All three articles stress the need for a multidisciplinary approach to HF management, involving cardiologists, nurses, pharmacists, and other healthcare professionals. This team-based care is crucial for optimizing treatment and improving patient outcomes.

POLICY HISTORY

Date	Summary
December 2025	<ul style="list-style-type: none"> Added the following CPT Codes to reflect Evolent prior authorization scope: 76932
June 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> Added new bullet-point to the General Statement section No clinical changes
December 2024	<ul style="list-style-type: none"> This guideline replaces UM 1388 Endomyocardial Biopsy Updated references Revised heart transplant monitoring schedule to conform with

Date	Summary
	new professional guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7287 for Endovascular Femoropopliteal Interventions

Guideline Number: Evolent_CG_7287	<u>Applicable Codes</u>	
<i>"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc.</i> <i>© 2011 - 2026 Evolent. All rights Reserved.</i>		
Original Date: September 2011	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Endovascular Femoropopliteal Interventions.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS

Documentation Requirements

In addition to the procedure-specific indications described throughout this guideline, the provided notes **MUST** also meet the following criteria:

- Shared Decision-Making Process ⁽⁶⁾
 - Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including open surgical bypass, and their potential outcomes. This process must be described. ⁽⁶⁾

Records cannot imply that failure to treat claudication can result in amputation. If atherectomy is being considered records must include evidence that the member has been informed that there is no current proof that atherectomy has added clinical benefit in comparison to PTA.

- Complexity of the Procedure
 - Procedures can be straightforward or complex. A complex procedure is defined as one where the lesion being treated has caused a total occlusion. Documentation of occlusion can be provided by submitting:
 - the report from a CTA, MRA or angiogram demonstrating occlusion
 - a duplex scan report that confirms occlusion of the artery, as evidenced by no detectable color or spectral flow despite technical optimization and imaged evidence of collaterals with monophasic/absent flow distally. The report must also identify the artery(s) imaged.
- Anatomical Location
 - For the purpose of this guideline, the femoropopliteal anatomical region is divided into two areas, and the notes must detail which region(s) will be treated:
 - Common and deep femoral arteries (see **Limitations**)
 - Superficial Femoral and popliteal arteries.

Angioplasty

- The type of balloon (plain or drug-eluting) should be described in the prior authorization request or procedure note. ^(6,7)

Stent ⁽⁸⁾

Primary stenting is medically necessary and preferred when percutaneous transluminal angioplasty alone is not expected to provide a durable result for patients. ⁽⁸⁾ Examples include:

- Arterial occlusions or highly irregular lesions that carry an elevated risk for distal embolization or rapid recurrence
- Significantly calcified lesions, eccentric lesions, or lesions related to external compression, or ostial lesions
- Lesions longer than 5cm
- The type of stent (Drug eluting, covered or plain) that will be/is used should be described in the prior authorization request or procedural note

Atherectomy

The term atherectomy applies to a number of different approved devices which may decrease arterial wall thickness, improve patency, and decrease the need for stenting. **However, due to insufficient evidence for widespread use, Evolent will only approve Atherectomy for the following indications ⁽⁸⁾:**

- Lesions proven to be resistant to angioplasty during a prior procedure
- Heavily calcified lesions as evidenced by CTA, angiography, intravascular ultrasound or prior duplex scan
- Complete occlusions
- Symptomatic and verified in-stent restenosis as verified by noninvasive criteria listed below in the section “Other Indications”

Lithotripsy

Lithotripsy involves delivery of high intensity ultrasound via an intraarterial catheter to break up vascular wall calcification to enable more effective angioplasty. Either lithotripsy or atherectomy can be used but not for the same lesion. Indications include any of the following ⁽⁹⁾:

- Calcified lesions proven to be resistant to angioplasty during a prior procedure
- Heavily calcified lesions causing at least a 70% reduction in diameter as evidenced by CTA, angiography, intravascular ultrasound or prior duplex scan

Claudication (6,7,10,11)

When **ALL** the following requirements have been met:

- Impairment of activities of daily living and/or work
- Absence of other conditions that would limit exercise even if claudication is improved (e.g. arthritis, angina, chronic respiratory disease)
- Member is on guideline-directed medical therapy (GDMT)
- Inadequate response to a supervised or structured exercise program for 12 weeks (see **Definitions**)
- Proximal clinically significant aortoiliac disease is not present or successfully treated such that it is unlikely to be responsible for ongoing claudication.
- A noninvasive study such as:
 - A resting Ankle Brachial Index (ABI) <0.9 OR
 - Toe-brachial-index (TBI) <0.7 OR
 - 20% reduction in ankle pressure on exercise testing OR
 - If the ABI is >1.4, incompressible, or unobtainable due to local conditions, then:
 - TBI <0.7,
 - Absent or monophasic Doppler tracings or Pulse Volume Recordings (PVR)
- Femoral or popliteal arteries with anatomically suitable lesion(s) (see **Definitions**) for intervention with one of the following:
 - ≥70% stenosis on angiography (e.g., CTA, invasive angiography, MRA) ⁽¹⁰⁾ OR
 - Duplex ultrasound with no flow or stenosis with peak systolic velocity (PSV) ≥300

cm/s, or PSV ratio ≥ 4.0 with distal monophasic flow pattern in all tibial arteries

Chronic Limb Threatening Ischemia (10–12)

Chronic limb Threatening ischemia (CLTI) is present when there are nonhealing wounds, gangrene or rest pain. For the purposes of this guideline Rest Pain has its own noninvasive physiological requirements.

When ALL the following requirements have been met:

- Gangrene or non-healing ischemic wounds present for more than two weeks despite provider directed and described wound care **OR** wound Grade 1-3 based on The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wiffl), **AND** at least one of the following non-invasive studies:
 - An ABI < 0.9 OR
 - Ankle pressure < 100 mmHg OR
 - Toe pressures or TCPO₂ < 60 mmHg OR
 - If ABI ≥ 1.4 then one of the following:
 - Toe pressures or TCPO₂ < 60 mmHg OR
 - Flat line or monophasic PVR or Doppler waveforms in all of the tibial arteries or the tibial artery supplying the involved angiosome
- If no Gangrene or non-healing wounds but REST PAIN, then with ANY of the following:
 - Flat line or monophasic < 5 mm amplitude PVR or Doppler waveforms OR
 - ABI < 0.4 OR
 - If ankle pressure is unrecordable, toe pressure or TcPO₂ < 30 mmHg
- Proximal clinically significant aortoiliac disease is not present or has been successfully treated such that it is unlikely to be responsible for ongoing CLTI, OR will be treated concurrently with the femoropopliteal procedure
- Femoral or popliteal arteries with one of the following:
 - $\geq 50\%$ stenosis on angiography (e.g., computed tomography angiography, invasive angiography, magnetic resonance angiography) OR
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥ 250 cm/s or PSV ratio ≥ 2.0

Other Indications (10,12)

When at least one of the following requirements has been met:

- For the treatment of in-stent stenosis or occlusion associated with new or recurrent rest pain or claudication, or new or persistent ulceration or gangrene, and at least one of the following):
 - A drop in ABI of $\geq 20\%$,

- A peak systolic velocity of ≥ 300 cm/sec
- A tripling of velocity across the stenosis
- A translesional mean pressure gradient of ≥ 10 mmHg
- A systolic gradient of ≥ 20 mmHg
- Stent occlusion documented by an imaging study
- For the treatment of stenosis within a vein bypass graft in a member with new, progressive, or recurrent symptoms, or new, persistent, or lack of improvement in CLTI **(AUC Score 7)** ⁽¹³⁾
- For the treatment of stenosis within a vein bypass graft in an asymptomatic patient with concern for impending graft failure with one of the following **(AUC Score 7)** ^(13,14) :
 - Peak Systolic Velocity (PSV) of ≥ 180 cm/sec
 - A velocity ratio of ≥ 2.0
 - An end diastolic velocity of < 45 cm/sec
- For the treatment of stenosis within a prosthetic bypass graft with concern for impending graft failure **AND** an end diastolic velocity of < 45 cm/sec **(AUC Score 7)** ⁽¹⁴⁾
- For the treatment of femoropopliteal aneurysms with any of the following ⁽¹⁵⁾:
 - ≥ 20 mm diameter
 - 10-19 mm diameter with thrombus and at least one of the following:
 - Evidence of distal embolization
 - Poor distal runoff
- To allow local podiatric or orthopedic interventions when circulation may be tenuous but in and of itself not severe enough to warrant intervention; with ANY of the following:
 - An ABI < 0.8 OR
 - Ankle pressure < 100 mmHg OR
 - Toe Pressure or TcPO₂ < 60 mmHg OR
 - If ABI ≥ 1.4 then one of the following:
 - Toe Pressure or TcPO₂ < 60 mmHg OR
 - Monophasic PVR or Doppler waveforms

Limitations ^(10,11)

- Acute lower extremity ischemia is not considered in this policy
- Measurements of ankle perfusion using a photoplethysmography device which does not directly evaluate the dorsalis pedis and posterior tibial arteries individually (e.g. QuantaFlo® device), cannot be substituted for a doppler derived ABI (see **Definitions**)
- Intervention for PAD is not indicated in the absence of symptoms, ulceration, or

gangrene regardless of hemodynamic measures or imaging findings demonstrating PAD

- Requests to perform a subsequent intervention on the same limb must have documentation detailing new or worsening symptoms or findings, or persistent (>12 weeks) clinical indications
- Requests to perform the *same* intervention on the same anatomical location must have documentation detailing new or worsening symptoms or findings, or persistent (>12 weeks) clinical indications, supported by new noninvasive (see **Definitions**) and imaging studies, and a discussion about why other alternative treatments have not been considered
- Endovascular procedures are not indicated for non-ambulatory patients with a life expectancy <6 months and extensive lower extremity tissue necrosis. Consider primary amputation at the lowest level possible to ensure healing of the surgical site
- When tibial access is utilized to perform intervention on an artery proximal to that tibial artery, endovascular therapy of the transited artery is not indicated unless its treatment is required to revascularize a target distal to that transited tibial artery
- Endovascular treatment of Common femoral PAD involving the bifurcation or deep femoral artery is approvable for patients at high medical risk or at risk for local groin complications such as those with prior radiation, multiple prior surgeries, or infections. ^(7,16) If an endovascular procedure including the use of lithotripsy fails to improve the circulation, prior authorization will require documentation that the patient has been informed that surgical endarterectomy or bypass remain contraindicated or that the patient has refused such treatment.

CODING AND STANDARDS

Codes

37263, 37265, 37267, 37269, 37271, 37273, 37275, 37277, 76937, +37264, +37266, +37268, +37270, +37272, +37274, +37276, +37278

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- An **anatomically suitable lesion** is one where the appropriate intervention would have low risk, and a high probability of initial and long-term success (> 2 years) based on accepted lesion classifications such as TASC II or GLASS. ⁽¹⁰⁾
- **Ankle Brachial Index** is measured using a doppler device and pressure cuffs by dividing the highest brachial blood pressure in either arm by the highest pressure obtained from the dorsalis pedis or posterior tibial artery.
- **Chronic Limb Threatening Ischemia (CLTI)** has replaced Critical Limb Ischemia (CLI) since the threat to limb viability in patients with PAD is not only related to ischemia but other factors such as infection, neuropathy, and general patient morbidities. Further, “critical” implies that treatment is urgent to avoid limb loss, while some patients can keep their legs for extended periods of time even in the absence of revascularization. CLTI is defined clinically by the presence of rest pain, gangrene, a nonhealing wound or ulceration lasting more than 2 weeks despite appropriate wound care. Infection may make invasive treatment more urgent. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wifl) is helpful in defining CLTI and prognosticating indications for treatment and outcome. ⁽¹²⁾
- **Claudication** is a symptom complex of pain that begins with ambulation and that is relieved within a brief time by walking cessation. It is described by the intensity of discomfort, the distance walked, the duration of the walk and the impact that it has on quality of life (QOL) and activities of daily living (ADL). Claudication does not occur at rest. If left untreated, the natural history of claudication is slow progression, yet amputation is rare occurring in less than 5% of patients.
- **Clinically significant disease** is such that it is likely causing ischemic symptoms or findings
- **Endovascular intervention** is the treatment of peripheral arterial disease with angioplasty, atherectomy, intravascular lithotripsy, or stents. It is performed by opening the blood vessel with a device placed on a catheter inserted through a blood vessel. In some cases, drug elution is added to the device to prevent restenosis. Intravascular ultrasound and filters may assist the procedure. In some circumstances mechanical thrombectomy or drug infusion thrombolysis may be required.
- **Guideline Directed Medical Therapy (GDMT)** includes recommendations for antiplatelet therapy, cilostazol (unless contraindicated or not tolerated), statins, glycemic and hypertension control, structured exercise program, smoking cessation including planning, counseling, or behavior modification and pharmacotherapy if needed. Duration should be for at least 12 weeks.
- **Noninvasive tests/studies** include ABI, TBI, Toe pressures, TCPO₂, PVR or Doppler tracings. A duplex scan is noninvasive but for the purposes of this guideline is considered an imaging study.
- **Rest Pain** is a distinct pain syndrome lasting more than 2 weeks, implying CLTI. It is defined as pain in the foot or toes aggravated by elevation and relieved by dependency.

Nocturnal pain is not necessarily rest pain since there are other causes of pain at night. Rest pain does not usually imply the same urgency for treatment as gangrene or nonhealing wounds.

- **Structured exercise program** is provider-directed and monitored. It involves walking for 30-60 minutes at least 3 times a week for at least 12 weeks. Claudication is not a contraindication to a trial of exercise
- **Toe Brachial Index** is measured by dividing the highest brachial arm pressure by the pressure obtained from the first toe by any method. Unlike the ABI, the toe pressures are usually not affected by arterial calcification.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ABI: Ankle Brachial Index

AR: Authorization Request

AUC: Appropriate use criteria

CFA: Common Femoral Artery

CLI: Chronic limb ischemia

CLTI: Chronic limb threatening ischemia

CTO: Chronic total occlusion

CTA: Computed Tomography Angiography

DFA: Deep Femoral Artery

DSA: Digital Subtraction Angiography

EDV: End Diastolic Velocity

GDMT: Guideline directed medical therapy

GLASS: Global Anatomic Staging System

ISR: In-stent restenosis

PAD: Peripheral artery disease

PTA: Percutaneous transluminal angioplasty

PVR: Pulse Volume Recording

SFA: Superficial Femoral Artery

TASC: Trans-Atlantic Inter-Society Consensus

TBI: Toe Brachial Index

WIFI Classification: Wound, Ischemia, and Foot Infection

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions. For PAD structured exercise and Cilostazol are added to the Guidelines.

SUMMARY OF EVIDENCE

ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention ⁽¹⁰⁾

Study Design: This study involved the development of Appropriate Use Criteria (AUC) for peripheral artery intervention (PAI). The process included drafting patient scenarios, assumptions, and definitions based on published guidelines, trial data, and expert opinions. The scenarios were evaluated by an independent rating panel using a scoring scale from 1 to 9.

Target Population: The study focused on patients with peripheral artery disease (PAD) who may require revascularization treatments. This includes patients with renal artery stenosis, lower extremity disease, critical limb ischemia, asymptomatic artery disease, and secondary treatment options for lower extremity disease.

Key Factors:

Clinical Scenarios: 45 clinical scenarios with up to 6 intervention options per scenario were developed and categorized into 6 general sections.

Scoring: Each indication was scored as “Appropriate” (7 to 9), “May Be Appropriate” (4 to 6), or “Rarely Appropriate” (1 to 3).

Emphasis: Adherence to medical therapy was emphasized, with revascularization considered when medical therapy is insufficient.

Endovascular and Surgical Approaches: Both approaches were deemed appropriate in scenarios involving tissue loss or end organ compromise, with a tendency to select endovascular approaches.

2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease ⁽¹¹⁾

Study Design: This document is the 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management

of lower extremity peripheral artery disease. It was developed by the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines in collaboration with several other organizations.

Target Population: The guidelines are intended for clinicians treating patients with lower extremity peripheral artery disease across its multiple clinical presentation subsets, including asymptomatic PAD, chronic symptomatic PAD, chronic limb-threatening ischemia, and acute limb ischemia.

Key Factors: The document provides comprehensive recommendations on the clinical assessment, diagnostic testing, medical therapy, preventive foot care, exercise therapy, revascularization techniques, management of chronic limb-threatening ischemia, and acute limb ischemia. It also addresses special considerations such as risk amplifiers, health disparities, and management of PAD in older patients.

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (Wifl) ⁽¹²⁾

Study Design: This document introduces the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System, known as Wifl (Wound, Ischemia, and foot Infection).

Target Population: The classification system is designed for patients with threatened lower extremities due to chronic ischemia, particularly those with diabetes and diabetic foot ulcers.

Key Factors: The Wifl system stratifies patients based on the severity of wounds, ischemia, and infection. It aims to provide a more precise description of disease burden and improve outcomes analysis for various therapies. The system includes four grades for each factor and uses a Delphi consensus process to estimate the risk of amputation and the benefit of revascularization.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(10–12)

- All three documents emphasize the importance of medical therapy and structured exercise before considering revascularization for femoropopliteal interventions.
- Endovascular revascularization is recommended for patients with claudication not responsive to medical therapy and structured exercise.
- There is a preference for stenting in longer lesions, with drug-coated balloons and drug-eluting stents being highlighted as effective options.

In summary, while all three documents support the use of endovascular femoropopliteal interventions for patients with claudication not responsive to medical therapy and structured exercise, they differ in their emphasis on the criteria for revascularization, the importance of a multispecialty care team, and the consideration of wound, ischemia, and infection severity.

Evolent Clinical Guideline 7288 for Endovascular Aortoiliac Interventions

Guideline Number: Evolent_CG_7288	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Endovascular Aortoiliac Interventions.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS

Documentation Requirements

In addition to the procedure-specific indications described throughout this guideline, the provided notes **MUST** also meet the following criteria:

- Shared Decision-Making Process ^(6,7)
 - Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including open surgical bypass, and their potential outcomes. This process must be described. ⁽⁸⁾

Records cannot imply that failure to treat claudication can result in amputation.

- Complexity of the Procedure
 - Procedures can be straightforward or complex. A complex procedure is defined as one where the lesion being treated has caused a total occlusion. Documentation of occlusion can be provided by submitting:
 - the report from a CTA, MRA or angiogram demonstrating occlusion
 - a duplex scan report that confirms occlusion of the artery, as evidenced by no detectable color or spectral flow despite technical optimization and imaged evidence of collaterals with monophasic/absent flow distally. The report must also identify the artery(s) imaged.
- Anatomical Location
 - For the purpose of this guideline, the iliac anatomical region is divided into three areas, Common, internal, and external iliac arteries and the notes must detail which region(s) will be treated:

Angioplasty

- The type of balloon (plain or drug-eluting) should be described in the prior authorization request or procedure note.

Stents ⁽⁹⁾

Primary stenting is medically necessary and preferred when percutaneous transluminal angioplasty alone is not expected to provide a durable result for patients. ⁽⁶⁾ Examples include:

- Arterial occlusions or highly irregular lesions that carry an elevated risk for distal embolization or rapid recurrence
- Significantly calcified lesions, eccentric lesions, or lesions related to external compression, or ostial lesions
- Lesions longer than 5cm
- The type of stent (Drug eluting, covered or plain) that will be/is used should be described in the prior authorization request or procedural note.

Lithotripsy

Involves delivery of high intensity ultrasound via an intraarterial catheter to break up vascular wall calcification to enable more effective angioplasty. Indications include any of the following ⁽¹⁰⁾:

- Calcified lesions proven to be resistant to angioplasty during a prior procedure
- Heavily calcified lesions causing at least a 70% reduction in diameter as evidenced by CTA, angiography, intravascular ultrasound or prior duplex scan

Claudication (6–8,11)

When **ALL** the following requirements have been met (AUC SCORE 8):

- Impairment of activities of daily living and/or work
- Absence of other conditions that would limit exercise even if claudication is improved ⁽⁸⁾ (e.g., arthritis, angina, chronic respiratory disease)
- Member is on guideline-directed medical therapy (GDMT)
- Inadequate response to a supervised or structured exercise program for 12 weeks
- A resting Ankle Brachial Index (ABI) of abnormal (≤ 0.9) or noncompressible (>1.4):
 - TBI < 0.7
 - 20% reduction in ankle pressure on exercise testing

NOTE: If arteries are noncompressible (ABI > 1.40), making these tests unreliable, abnormal Doppler tracings or pulse volume recordings (PVR) can be provided

- Aortoiliac arteries with lesion(s) anatomically suited to intervention, with one of the following:
 - $\geq 70\%$ stenosis on angiography (e.g., CTA, invasive angiography, MRA) ⁽⁸⁾
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥ 300 cm/s **OR** PSV ratio ≥ 4.0 and with monophasic flow pattern ⁽¹²⁾

Chronic Limb Threatening Ischemia (8,11,13)

Chronic limb Threatening ischemia (CLTI) is present when there are nonhealing wounds, gangrene or rest pain. For the purposes of this guideline Rest Pain has its own noninvasive physiological requirements.

When the following requirements have been met (AUC SCORE 9):

- Gangrene or non-healing ischemic wounds present for more than two weeks despite provider directed and described wound care **OR** wound Grade 1-3 based on The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wiffl). One of the following must also be present:
 - ABI < 0.8
 - Ankle pressure < 100 mmHg
 - Toe pressures or TCPO₂ < 60 mmHg
 - TBI < 0.7
 - If ABI > 1.3 , then one of the:
 - Toe pressures or TCPO₂ < 60 mmHg
 - TBI < 0.7
 - Monophasic PVR or doppler waveforms

- If no Gangrene or non-healing wounds but rest pain, then with ANY of the following:
 - ABI < 0.4
 - If ankle pressures unrecordable, toe pressure or TcPO₂ < 30 mmHg
 - PVR amplitude or Doppler waveforms showing flat line or < 5mm with absent diastolic notch
- Aortoiliac arteries with anatomically suitable lesion(s) (see **Definitions**) for intervention with one of the following:
 - ≥50% stenosis on angiography (e.g., CTA, invasive angiography, MRA) or resting mean or hyperemic translesional pressure gradient of ≥ 10 mmHg
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥200 cm/s or PSV ratio ≥2 and with biphasic or monophasic flow pattern distally

Other Indications (8,13)

When at least one of the following requirements have been met:

- To provide access for large bore devices required for treating pathology proximal to the abdominal aorta. Examples include:
 - Transaortic Valve Replacement (TAVR)
 - Extracorporeal Membrane Oxygenation (ECMO)
- To provide access for implanting endovascular devices for the treatment of Abdominal Aortic Aneurysms
- For the treatment of in-stent stenosis associated with new or recurrent rest pain or claudication, or new or persistent ulceration or gangrene, and at least one of the following criteria:
 - A drop in ABI of ≥20%
 - A peak systolic velocity of ≥300 cm/s
 - A tripling of velocity across the stenosis
 - A translesional mean pressure gradient of ≥10 mmHg
 - A systolic gradient of 20 mmHg
- For the treatment of symptomatic or asymptomatic covered in-stent stenosis confirmed by a drop in ABI of ≥20%, or one of the following criteria:
 - A peak systolic velocity of ≥300 cm/sec
 - A tripling of velocity across the stenosis,
 - A translesional mean pressure gradient of 10 mmHg
 - A systolic gradient of ≥20 mmHg
- To allow local podiatric or orthopedic interventions when circulation may be tenuous but

in and of itself not severe enough to warrant intervention; with ANY of the following **(AUC SCORE 7)**:

- An ABI < 0.8
- Ankle pressure < 100mmHg
- Toe Pressure or TcPO₂ < 60mmHg
- If ABI ≥ 1.4, then one of the following:
 - Toe Pressure or TcPO₂ < 60mmHg
 - Monophasic PVR or Doppler waveforms
- Internal iliac intervention may be appropriate for buttock claudication or vasculogenic impotence provided it is supported by noninvasive testing ⁽⁹⁾

Limitations ^(8,11)

- Acute lower extremity ischemia is not considered in this policy
- Atherectomy of the aortoiliac arteries is not considered medically reasonable or necessary
- Intervention for PAD is not indicated in the absence of symptoms, ulceration, or gangrene regardless of hemodynamic measures or imaging findings demonstrating PAD
- Requests to perform a subsequent intervention on the same limb must have documentation detailing new symptoms or findings, or persistence (>12 weeks) of clinical indications, supported by new physiologic and imaging studies. A discussion about why other alternative treatments have not been considered is necessary.
- Measurements of ankle perfusion using a photoplethysmography device which does not directly evaluate the dorsalis pedis and posterior tibial arteries individually (e.g. QuantaFlo® device), cannot be substituted for a doppler derived ABI (see **Definitions**)
- Endovascular procedures are not indicated for non-ambulatory patients with a life expectancy <6 months and extensive lower extremity tissue necrosis. Consider primary amputation at the lowest level possible to ensure healing of the surgical site

CODING AND STANDARDS

Codes

37254, 37256, 37258, 37260, +37255, +37257, +37259, +37261

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- An **anatomically suitable lesion** is one where the appropriate intervention would have low risk, and a high probability of initial and long-term success (> 2 years) based on accepted lesion classifications such as TASC II or GLASS. ^(7,8)
- **Ankle Brachial Index (ABI)** is measured by dividing the highest brachial blood pressure in either arm by the highest pressure obtained from the dorsalis pedis or posterior tibial artery.
- **Chronic Limb Threatening Ischemia (CLTI)** has replaced Critical Limb Ischemia (CLI) since the threat to limb viability in patients with PAD is not only related to ischemia but other factors such as infection, neuropathy, and general patient morbidities. Further, "critical" implies that treatment is urgent to avoid limb loss, while some patients can keep their legs for extended periods of time even in the absence of revascularization. CLTI is defined clinically by the presence of rest pain, gangrene, a nonhealing wound or ulceration lasting more than 2 weeks despite appropriate wound care. Infection may make invasive treatment more urgent. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (WIfI) is helpful in defining CLTI and prognosticating indications for treatment and outcome. ⁽¹³⁾
- **Claudication** is a symptom complex of pain that begins with ambulation and that is relieved within a brief time by walking cessation. It is described by the intensity of discomfort, the distance walked, the duration of the walk and the impact that it has on quality of life (QOL) and activities of daily living (ADL). Claudication does not occur at rest. If left untreated, the natural history of claudication is slow progression, yet amputation is rare occurring in less than 5% of patients.
- **Clinically significant disease** is such that it is likely causing ischemic symptoms or findings.
- **Endovascular intervention** is the treatment of peripheral arterial disease with angioplasty, atherectomy, intravascular lithotripsy, or stents. It is performed by opening the blood vessel with a device placed on a catheter inserted through a blood vessel. In

some cases, drug elution is added to the device to prevent restenosis. Intravascular ultrasound and filters may assist the procedure. In some circumstances mechanical thrombectomy or drug infusion thrombolysis may be required.

- **Guideline Directed Medical Therapy (GDMT)** includes recommendations for antiplatelet therapy, cilostazol (unless contraindicated or not tolerated), statins, glycemic and hypertension control, structured exercise program, smoking cessation including planning, counseling, or behavior modification and pharmacotherapy if needed. Duration should be for at least 12 weeks.
- **Physiologic studies** include ABI, TBI, Toe pressures, TCPO₂, PVR or Doppler tracings
- **Rest Pain** is a distinct pain syndrome lasting more than 2 weeks, implying CLTI. It is defined as pain in the foot or toes aggravated by elevation and relieved by dependency. Nocturnal pain is not necessarily Rest Pain since there are other causes of pain at night. Rest pain does not usually imply the same urgency for treatment as gangrene or nonhealing wounds.
- **Structured exercise program** is provider-directed and monitored. It involves walking for 30-60 minutes at least 3 times a week for at least 12 weeks. Claudication is not a contraindication to a trial of exercise ⁽⁶⁾
- **Toe Brachial Index** is measured by dividing the highest brachial arm pressure by the pressure obtained from the first toe by any method. Unlike the ABI, the toe pressures are usually not affected by arterial calcification.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ABI: Ankle Brachial Index

AUC: Appropriate use criteria

CFA: Common femoral artery

CLTI: Chronic limb Threatening ischemia

CTA: Computed Tomography Angiography

CTO: Chronic Total Occlusion

DSA: Digital Subtraction Angiography

EIA: External iliac artery

ECMO: Extracorporeal membrane oxygenation

GDMT: Guideline directed medical therapy

GLASS: Global Anatomic Staging System

ISR: In-stent stenosis

PAD: Peripheral arterial disease

PSV: Peak systolic velocity

PTA: Percutaneous transluminal Angioplasty

PVR: Pulse Volume Recording

TASC: Trans-Atlantic Inter-Society Consensus

TAVR: Transaortic valve replacement

TBI: Toe brachial index

WIFI Classification: Wound, Ischemia, and Foot Infection

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions. For PAD, structured exercise and Cilostazol are added to the Guidelines.

SUMMARY OF EVIDENCE

ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention ⁽⁸⁾

Study Design: This study involved the development of Appropriate Use Criteria (AUC) for peripheral artery intervention (PAI). The process included drafting patient scenarios, assumptions, and definitions based on published guidelines, trial data, and expert opinions. The scenarios were evaluated by an independent rating panel using a scoring scale from 1 to 9.

Target Population: The study focused on patients with peripheral artery disease (PAD) who may require revascularization treatments. This includes patients with renal artery stenosis, lower extremity disease, critical limb ischemia, asymptomatic artery disease, and secondary treatment options for lower extremity disease.

Key Factors:

Clinical Scenarios: 45 clinical scenarios with up to 6 intervention options per scenario were developed and categorized into 6 general sections.

Scoring: Each indication was scored as “Appropriate” (7 to 9), “May Be Appropriate” (4 to 6), or “Rarely Appropriate” (1 to 3).

Emphasis: Adherence to medical therapy was emphasized, with revascularization considered when medical therapy is insufficient.

Endovascular and Surgical Approaches: Both approaches were deemed appropriate in scenarios involving tissue loss or end organ compromise, with a tendency to select endovascular approaches.

2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease ⁽¹¹⁾

Study Design: This document is the 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease. It was developed by the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines in collaboration with several other organizations.

Target Population: The guidelines are intended for clinicians treating patients with lower extremity peripheral artery disease across its multiple clinical presentation subsets, including asymptomatic PAD, chronic symptomatic PAD, chronic limb-threatening ischemia, and acute limb ischemia.

Key Factors: The document provides comprehensive recommendations on the clinical assessment, diagnostic testing, medical therapy, preventive foot care, exercise therapy, revascularization techniques, management of chronic limb-threatening ischemia, and acute limb ischemia. It also addresses special considerations such as risk amplifiers, health disparities, and management of PAD in older patients.

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (Wifl) ⁽¹³⁾

Study Design: This document introduces the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System, known as Wifl (Wound, Ischemia, and foot Infection).

Target Population: The classification system is designed for patients with threatened lower extremities due to chronic ischemia, particularly those with diabetes and diabetic foot ulcers.

Key Factors: The Wifl system stratifies patients based on the severity of wounds, ischemia, and infection. It aims to provide a more precise description of disease burden and improve outcomes analysis for various therapies. The system includes four grades for each factor and uses a Delphi consensus process to estimate the risk of amputation and the benefit of revascularization.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(8,11,13)

- All three documents emphasize the importance of medical therapy and structured exercise before considering revascularization for femoropopliteal interventions.
- Endovascular revascularization is recommended for patients with claudication not responsive to medical therapy and structured exercise.

- There is a preference for stenting in longer lesions, with drug-coated balloons and drug-eluting stents being highlighted as effective options.

In summary, while all three documents support the use of endovascular femoropopliteal interventions for patients with claudication not responsive to medical therapy and structured exercise, they differ in their emphasis on the criteria for revascularization, the importance of a multispecialty care team, and the consideration of wound, ischemia, and infection severity.

POLICY HISTORY

Date	Summary
December 2025	<ul style="list-style-type: none"> • Codes within the Coding section were edited to reflect changes made by the American Medical Association. Deleted: 37220, 37221, 37222, 37223. Added: 37254, 37256, 37258, 37260, +37255, +37257, +37259, +37261 • Added Shared decision making • Added documentation requirements • Added indications for Atherectomy and Lithotripsy • Added description of Complexity • Added new definition of Anatomical regions • Clarified noninvasive test requirements • Added indications for access to iliac arteries • Updated references
June 2025	<ul style="list-style-type: none"> • Updated citations • Added AUC scores • Added third bullet to General Information • Checked Medicare Advantage Line of Business • Added Summary of Evidence and Analysis of Evidence
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1172 for Endovascular Iliac Interventions <ul style="list-style-type: none"> ◦ The guideline name has been changed to Endovascular Aortoiliac Interventions • Clinical indications were updated per societal guidance

Evolent Clinical Guideline 7289 for Endovascular Infrapopliteal (Tibioperoneal) Interventions

Guideline Number: Evolent_CG_7289	<u>Applicable Codes</u>	
<i>"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc.</i> <i>© 2011 - 2026 Evolent. All rights Reserved.</i>		
Original Date: September 2011	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Endovascular Infrapopliteal (Tibioperoneal) Interventions.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS

Documentation Requirements

In addition to the procedure-specific indications described throughout this guideline, the provided notes **MUST** also meet the following criteria:

- Shared Decision-Making Process ^(6,7)
 - Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including open

surgical bypass, and their potential outcomes. This process must be described. ⁽⁶⁾ Records cannot imply that failure to treat claudication can result in amputation. If atherectomy is being considered records must include evidence that the member has been informed that there is no current proof that atherectomy has added clinical benefit in comparison to PTA.

- Complexity of the Procedure
 - Procedures can be straightforward or complex. A complex procedure is defined as one where the lesion being treated has caused a total occlusion. Documentation of occlusion can be provided by submitting:
 - the report from a CTA, MRA or angiogram demonstrating occlusion
 - a duplex scan report that confirms occlusion of the artery, as evidenced by no detectable color or spectral flow despite technical optimization and imaged evidence of collaterals with monophasic/absent flow distally. The report must also identify the artery(s) imaged.
- Anatomical Location
 - For the purpose of this guideline, there are three tibial arteries, the Anterior and Posterior Tibial and the Peroneal artery. Treatment of the tibioperoneal artery will only be considered as a separate vessel if it is the only “Tibial” being treated. Otherwise, it is considered as part of either the Posterior Tibial or the Peroneal artery.

Angioplasty

- The type of balloon (plain or drug-eluting) should be described in the prior authorization request or procedure note.

Stents

Primary stenting tibial arteries is rarely appropriate. However, secondary stenting may be medically necessary for ⁽⁸⁾:

- Arterial occlusions or highly irregular lesions that carry an elevated risk for distal embolization or rapid recurrence
- Lack of response to angioplasty despite maximal approvable inflation pressures
- If a stent is used, the type of stent (drug eluting or plain) should be recorded

Atherectomy

The term atherectomy applies to a number of different approved devices which may decrease arterial wall thickness, improve patency, and decrease the need for stenting. However, due to insufficient evidence for widespread use, Evolent will only approve Atherectomy for the following indications ⁽⁸⁾:

- Lesions proven to be resistant to angioplasty during a prior procedure
- Heavily calcified lesions as evidenced by CTA, angiography, intravascular ultrasound or

prior duplex scan

- Complete occlusions
- Symptomatic and verified in-stent restenosis as verified by noninvasive criteria listed below in Other Indications

Claudication (6,7,9,10)

Revascularization of infra-popliteal PAD is generally limited to those patients presenting with critical limb threatening ischemia (CLTI). ⁽⁸⁾ However, infrequently, intervention may be indicated when **ALL** the following requirements have been met:

- **Severe** impairment of activities of daily living and/or work
- Absence of other conditions that would limit exercise even if claudication is improved (e.g. arthritis, angina, chronic respiratory disease)
- Member is on guideline-directed medical therapy (GDMT)
- Inadequate response to a supervised or structured exercise program for 12 weeks (see Definitions)
- Proximal clinically significant aortoiliac and/or femoropopliteal disease is not present or successfully treated such that it is unlikely to be responsible for ongoing claudication
- A resting Ankle Brachial Index (ABI) of abnormal (≤ 0.9) or noncompressible (>1.4) or either:
 - TBI <0.7
 - 20% reduction in ankle pressure during exercise testing
 - If arteries are noncompressible (ABI > 1.4) due to arterial calcification, or cannot be assessed due to local skin or wound conditions, abnormal Doppler waveforms or pulse volume recordings (PVR) can be provided
- Duplex ultrasound showing no flow or Doppler findings in all three tibial arteries with peak systolic velocities (PSV) ≥ 300 cm/s or PSV ratios ≥ 4.0 and with monophasic flow patterns
- $\geq 70\%$ stenosis in all three tibial arteries on angiography (e.g., CTA, invasive angiography, MRA)

NOTE: When claudication is the indication, authorization will be for the treatment of only one tibial artery

Chronic Limb Threatening Ischemia (9–11)

Chronic limb Threatening ischemia (CLTI) is present when there are nonhealing wounds, gangrene or rest pain. For the purposes of this guideline Rest Pain has its own noninvasive physiological requirements.

- Gangrene or non-healing ischemic wounds present for more than two weeks despite provider directed and described wound care **OR** wound Grade 1-3 based on The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System

(Wifi) AND

- Physiologic noninvasive studies which must include:
 - An ABI < 0.9
 - Ankle pressure < 100 mmHg
 - Toe pressures or TCPO₂ < 60 mmHg
 - If ABI ≥ 1.4, then one of the following:
 - Toe pressures or TCPO₂ < 60 mmHg
 - TBI < 0.7
 - PVR or Doppler waveforms with flat line tracing or monophasic tracings with amplitude <5mm.
- Infrapopliteal disease involving all three tibial arteries, or the anterior tibial and tibioperoneal trunk, or a single artery supplying the involved angiosome, with anatomically suitable lesion(s) (see **Definitions**), for intervention and documentation of any of the following within the involved tibial artery(s)⁽¹²⁾:
 - ≥50% stenosis on angiography (e.g., CTA, invasive angiography, MRA)⁽⁸⁾
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥250 cm/s **OR** PSV ≥2.0. When there is duplex or angiographic confirmation that the SFA or Popliteal has a severe stenosis or occlusion, ALL tibial arteries may show blunted velocities less than 250cm/sec. Then, provided there is an accompanying request to treat the occluded proximal femoropopliteal lesion, tibial intervention can also be approved if at least one tibial artery is also occluded.
- If no Gangrene or non-healing wounds but Rest Pain, then with ANY of the following:
 - ABI < 0.4
 - If ankle pressures unrecordable or unobtainable, toe pressure or TcPO₂ < 30 mmHg
 - PVR amplitude or Doppler waveforms showing flat line or monophasic with amplitude < 5 mm
 - Infrapopliteal disease in all 3 tibial arteries, or the anterior tibial and tibioperoneal trunk, with anatomically suitable lesion(s) (see **Definitions**), for intervention and documentation of any of the following in the artery(s) to be treated⁽¹²⁾:
 - ≥50% stenosis on angiography (e.g., CTA, invasive angiography, MRA)⁽⁸⁾
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥250 cm/s **OR** PSV ≥2.0. When there is duplex or angiographic confirmation that the SFA or Popliteal has a severe stenosis or occlusion, ALL tibial arteries may show blunted velocities less than 250cm/sec. Then, provided there is an accompanying request to treat the occluded proximal femoropopliteal lesion, tibial intervention can also be approved if at least two tibial arteries are also occluded.

- Proximal clinically significant aortoiliac and/or femoropopliteal disease is not present or has been successfully treated such that it is unlikely to be responsible for ongoing CLTI, **OR** will be treated concurrently with the tibial procedure

Other Indications (9,11)

- **Inframalleolar procedures** will be considered to treat continued poor healing or gangrene (not rest pain) only after a more proximal tibial intervention has not provided improvement and open bypass is not an alternative ⁽¹³⁾
- For the treatment of **in-stent** stenosis or occlusion associated with new or recurrent rest pain, or new or persistent ulceration or gangrene, and at least one of the following criteria:
 - A drop in ABI of $\geq 20\%$
 - A peak systolic velocity of ≥ 300 cm/s
 - A tripling of velocity across the stenosis
 - A translesional mean pressure gradient of ≥ 10 mmHg
 - A systolic gradient of ≥ 20 mmHg
 - Stent occlusion documented by an imaging study
- For the treatment of stenosis within a tibial vein bypass graft in a patient with new, progressive, or recurrent symptoms, or new, persistent, or lack of improvement in CLTI (AUC 7) ⁽¹⁴⁾
- For the treatment of stenosis within a tibial vein bypass graft in an asymptomatic patient with concern for impending graft failure with one of the following ^(14,15)
 - peak systolic velocity (PSV) of >180 cm/s
 - Velocity ratio of >2.0
 - an end diastolic velocity of <45 cm/s
- For the treatment of stenosis within a tibial prosthetic bypass graft with concern for impending graft failure **AND** an end diastolic velocity of <45 cm/s ⁽¹⁵⁾
- To allow local podiatric or orthopedic interventions when circulation may be tenuous but in and of itself not severe enough to warrant intervention, with ALL of the following:
 - Physiologic noninvasive studies which must include:
 - An ABI < 0.9
 - Ankle pressure < 100 mmHg
 - Toe pressures or TCPO₂ < 60 mmHg
 - If ABI ≥ 1.4 , then one of the following:
 - Toe pressures or TCPO₂ < 60 mmHg
 - TBI < 0.7

- PVR or Doppler waveforms with flat line tracing or monophasic tracings with amplitude <5mm.
- Infrapopliteal disease involving all three tibial arteries, or the anterior tibial and tibioperoneal trunk, or a single artery supplying the involved angiosome, with anatomically suitable lesion(s) (see **Definitions**), for intervention and documentation of any of the following within the involved tibial artery(s) ⁽¹²⁾:
 - ≥50% stenosis on angiography (e.g., CTA, invasive angiography, MRA) ⁽⁸⁾
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥250 cm/s **OR** PSV ≥2.0. When there is duplex or angiographic confirmation that the SFA or Popliteal has a severe stenosis or occlusion, ALL tibial arteries may show blunted velocities less than 250cm/sec. Then, provided there is an accompanying request to treat the occluded proximal femoropopliteal lesion, tibial intervention can also be approved if at least one tibial artery is also occluded.

Limitations ^(9,10)

- Acute lower extremity ischemia is not considered in this policy
- Measurements of ankle perfusion using a photoplethysmography instrument that does not directly evaluate flow in the dorsalis pedis and the posterior tibial artery (e.g. QuantaFlo® device), cannot be substituted for a doppler derived ABI (see definitions)
- Intervention for PAD is not indicated in the absence of symptoms, ulceration, or gangrene regardless of hemodynamic measures or imaging findings demonstrating PAD
- Requests to perform a subsequent intervention on the same limb must have documentation detailing new or worse symptoms or findings, or persistence (>12 weeks), supported by new physiologic (see **Definitions**) and imaging studies. **A discussion about why other alternative treatments have not been considered is necessary** and must be included in the documentation
- Endovascular procedures are not indicated for non-ambulatory patients with a life expectancy <6 months and extensive lower extremity tissue necrosis. Consider primary amputation at the lowest level possible to ensure healing of the surgical site
- When tibial access is utilized to perform intervention on an artery proximal to that tibial artery, endovascular therapy of the transited artery is not indicated unless its treatment is required to revascularize a target distal to that transited tibial artery
- Inframalleolar interventions are not considered necessary for the management of rest pain or claudication ⁽⁷⁾

CODING AND STANDARDS

Codes

37280, 37282, 37284, 37286, 37288, 37290, 37292, 37294, 37296, 37298, +37281, +37283, +37285, +37287, +37289, +37291, +37293, +37295, +37297, +37299

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- **Anatomically suitable lesion** is one where the appropriate intervention would have low risk, and a high probability of initial and long-term success (>2 years) based on accepted lesion classifications such as TASC II or GLASS. ⁽⁹⁾
- **Ankle Brachial Index (ABI)** is measured by dividing the highest brachial blood pressure in either arm by the highest pressure obtained from the dorsalis pedis or posterior tibial artery.
- **Chronic Limb Threatening Ischemia (CLTI)** has replaced Critical Limb Ischemia (CLI) since the threat to limb viability in patients with PAD is not only related to ischemia but other factors such as infection, neuropathy, and general patient morbidities. Further, "critical" implies that treatment is urgent to avoid limb loss, while some patients can keep their legs for extended periods of time even in the absence of revascularization. CLTI is defined clinically by the presence of Rest Pain, gangrene, a nonhealing wound or ulceration lasting more than 2 weeks despite appropriate wound care. Infection may make invasive treatment more urgent. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wifl) is helpful in defining CLTI and prognosticating indications for treatment and outcome. ⁽¹¹⁾
- **Claudication** is a symptom complex of pain that begins with ambulation and that is relieved within a brief time by walking cessation. It is described by the intensity of discomfort, the distance walked, the duration of the walk and the impact that it has on quality of life (QOL) and activities of daily living (ADL). Claudication does not occur at rest. If left untreated, the natural history of claudication is slow progression, yet

amputation is rare occurring in less than 5% of patients.

- **Clinically significant disease** is such that it is likely causing ischemic symptoms or findings.
- **Endovascular intervention** is the treatment of peripheral arterial disease with angioplasty, atherectomy, intravascular lithotripsy, or stents. It is performed by opening the blood vessel with a device placed on a catheter inserted through a blood vessel. In some cases, drug elution is added to the device to prevent restenosis. Intravascular ultrasound and filters may assist the procedure. In some circumstances mechanical thrombectomy or drug infusion thrombolysis may be required.
- **Guideline Directed Medical Therapy (GDMT)** includes recommendations for antiplatelet therapy, cilostazol (unless contraindicated or not tolerated), statins, glycemic and hypertension control, structured exercise program, smoking cessation including planning, counseling, or behavior modification and pharmacotherapy if needed. Duration should be for at least 12 weeks.
- **PAD:** Peripheral Arterial Disease
- **Physiologic studies** include ABI, TBI, Toe pressures, TCPO₂, PVR or Doppler tracings
- **Rest Pain** is a distinct pain syndrome lasting more than 2 weeks, implying CLTI. It is defined as pain in the foot or toes aggravated by elevation and relieved by dependency. Nocturnal pain is not necessarily Rest Pain since there are other causes of pain at night. Rest pain does not usually imply the same urgency for treatment as gangrene or nonhealing wounds.
- **Structured exercise program** is provider-directed and monitored. It involves walking to a pain threshold 3 times a week.
- **Toe Brachial Index** is measured by dividing the highest brachial arm pressure by the pressure obtained from the first toe by any method. Unlike the ABI, the toe pressures are usually not affected by arterial calcification.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ABI: Ankle Brachial Index

AR: Authorization Request

AUC: Appropriate use criteria

BMS: Bare metal stent
CFA: Common femoral artery
CLTI: Chronic limb Threatening ischemia
CTO: Chronic total occlusion
CTA: Computed Tomography Angiography
DFA: Deep Femoral Artery
DSA: Digital Subtraction Angiography
GDMT: Guideline directed medical therapy
GLASS: Global Anatomic Staging System
ISR: In-stent restenosis
PAD: Peripheral artery disease
PTA: Percutaneous transluminal angioplasty
PVR: Pulse Volume Recording
SFA: Superficial Femoral Artery
TASC: Trans-Atlantic Inter-Society Consensus
TBI: Toe Brachial Index
Wifl Classification: Wound, Ischemia, and Foot Infection

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions. For PAD structured exercise and Cilostazol are added to the Guidelines.

SUMMARY OF EVIDENCE

ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention⁽⁹⁾

Study Design: This study involved the development of Appropriate Use Criteria (AUC) for peripheral artery intervention (PAI). The process included drafting patient scenarios, assumptions, and definitions based on published guidelines, trial data, and expert opinions. The scenarios were evaluated by an independent rating panel using a scoring scale from 1 to 9.

Target Population: The study focused on patients with peripheral artery disease (PAD) who may require revascularization treatments. This includes patients with renal artery stenosis, lower

extremity disease, critical limb ischemia, asymptomatic artery disease, and secondary treatment options for lower extremity disease.

Key Factors:

Clinical Scenarios: 45 clinical scenarios with up to 6 intervention options per scenario were developed and categorized into 6 general sections.

Scoring: Each indication was scored as “Appropriate” (7 to 9), “May Be Appropriate” (4 to 6), or “Rarely Appropriate” (1 to 3).

Emphasis: Adherence to medical therapy was emphasized, with revascularization considered when medical therapy is insufficient.

Endovascular and Surgical Approaches: Both approaches were deemed appropriate in scenarios involving tissue loss or end organ compromise, with a tendency to select endovascular approaches.

2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease ⁽¹⁰⁾

Study Design: This document is the 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease. It was developed by the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines in collaboration with several other organizations.

Target Population: The guidelines are intended for clinicians treating patients with lower extremity peripheral artery disease across its multiple clinical presentation subsets, including asymptomatic PAD, chronic symptomatic PAD, chronic limb-threatening ischemia, and acute limb ischemia.

Key Factors: The document provides comprehensive recommendations on the clinical assessment, diagnostic testing, medical therapy, preventive foot care, exercise therapy, revascularization techniques, management of chronic limb-threatening ischemia, and acute limb ischemia. It also addresses special considerations such as risk amplifiers, health disparities, and management of PAD in older patients.

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIFI) ⁽¹¹⁾

Study Design: This document introduces the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System, known as WIFI (Wound, Ischemia, and foot Infection).

Target Population: The classification system is designed for patients with threatened lower extremities due to chronic ischemia, particularly those with diabetes and diabetic foot ulcers.

Key Factors: The WIFI system stratifies patients based on the severity of wounds, ischemia, and infection. It aims to provide a more precise description of disease burden and improve outcomes analysis for various therapies. The system includes four grades for each factor and uses a Delphi consensus process to estimate the risk of amputation and the benefit of revascularization.

Evolut Clinical Guideline 7290 for Treatment of Varicose Veins

Guideline Number: Evolut _CG_7290	<u>Applicable Codes</u>	
<i>"Evolut" refers to Evolut Health LLC and Evolut Specialty Services, Inc.</i> <i>© 2011 - 2026 Evolut. All rights Reserved.</i>		
Original Date: September 2011	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

GENERAL

- Varicose veins can be treated by different methods depending on the anatomy of the vein, and surgeon or patient preference
 - Anatomical features that can determine treatment include:
 - Spider veins
 - Reticular veins
 - Individual varicosities or clusters of varicose veins
 - Perforator veins
 - Truncal veins which include the greater saphenous, small saphenous, anterior accessory saphenous, posterior accessory saphenous

- Abnormalities of the deep veins do not constitute varicose veins, but may contribute to them
- Treatment methods include:
 - Conservative measures including compression, ambulation, limb elevation, and avoiding prolonged sitting and standing
 - High ligation and stripping
 - Stab avulsion Phlebectomy (SAP) also known as mini- or micro-phlebectomy
 - Cluster excision
 - Transilluminated powered phlebectomy
 - Sclerotherapy with polidocanol or sodium tetradecyl sulfate
 - Thermal ablation of truncal veins using laser or radiofrequency
 - Nonthermal ablation of truncal veins
 - Medical adhesive

INDICATIONS (6–9)

- Documentation of symptomatic venous disorders (see **Definitions**):
 - Any of the following with clinical issues attributed to venous reflux:
 - Axial reflux ≥ 500 ms and vein diameter ≥ 5 mm in the great saphenous vein or anterior accessory saphenous veins
 - Axial Reflux ≥ 500 ms and vein diameter ≥ 3 mm in the small saphenous vein
 - Axial Reflux >500 ms and vein diameter ≥ 5 mm in the posterior accessory vein provided all other axial reflux is absent, or successfully treated > 3 months previously, and patient has continued CEAP C2s or C4-C6
 - Perforator vein with reflux ≥ 500 milliseconds (ms) and diameter ≥ 3.5 mm **AND ANY** of the following:
 - It is located beneath an open venous ulcer and truncal reflux has been corrected or will be treated concurrently
 - It is Located beneath a healed venous ulcer and truncal reflux has been corrected
 - It lies directly beneath a symptomatic vein or cluster of veins with persistent or recurrent symptoms > 3 months after complete ablation of refluxing superficial truncal veins

Clinical issues attributed to venous reflux include **ANY** of the following:

- Leg or foot ulceration
- Hemorrhage or recurrent bleeding episodes from a ruptured varicosity or spider vein telangiectasia or reticular vein

- Superficial thrombophlebitis
- Severe and persistent pain and/or swelling that interferes with the quality of daily life (CEAP class C2s or greater) and persists despite 6 weeks of conservative measures (see Definition), unless contraindicated (e.g. suspected or proven peripheral arterial disease, severe peripheral neuropathy)
- Spider and reticular veins that have bled or in the elderly judged to be a substantial risk for hemorrhage with minimal trauma
- C6 with below the knee reflux in the great saphenous vein ≥ 500 ms and vein diameter ≥ 3 mm

Treatment Plans for Bilateral Interventions (6–9)

- The planned treatment/s must be completed within 90 days from the first treatment.
- When Truncal treatment is the primary treatment and Sclerotherapy or SAP is also being considered for that extremity, SAP and/or sclerotherapy should be performed with Truncal treatment unless:
 - There are extensive varicosities
 - There are circumferential limb varicosities requiring changing the patient's position from supine to decubitus
 - There is a need for general anesthesia or large amounts of local or tumescent anesthetic
- Ablation of two continuous saphenous segments accessed by a single or multiple access points is still considered a single ablation
- If both the AASV and great saphenous require treatment both should be treated concurrently unless a reason is specified
- A treatment plan that involves three truncal veins/leg must have detailed explanation and identify the proposed sequence of treatments

LIMITATIONS (6–9)

- Failure of ablation or recurrent venous reflux without other indications for treatment
- Bilateral leg edema (CEAP C3) unless other reasons for edema have been discussed and excluded
- Ultrasound guided foam sclerotherapy for truncal and varicose veins >6 mm
- Nonthermal techniques for truncal veins ≥ 10 mm
- Ablation by thermal or nonthermal techniques for venous aneurysms located within 3 cm of saphenofemoral junctions
- Isolated saphenofemoral junctional incompetence

- Isolated reflux in great saphenous vein segments, in the presence of competent segments proximally and distally
- Previous administration of sclerotherapy agent in the same vein less than 6 weeks prior
- The following are contradictions to intervention
 - Allergy to sclerotherapy agents
 - Pregnancy or within 3 months after delivery
 - Acute febrile illness
 - Local or general infection
 - Severe distal arterial occlusive disease (ankle brachial index <0.4 arterial ulcer or gangrene)
 - Obliteration of the deep venous system
 - Acute deep venous phlebitis
 - Prolonged immobility
 - Ultrasound guided foam sclerotherapy in a patient with symptomatic right to left shunt
 - Eminent requirement of the great or small saphenous vein for an arterial or coronary artery bypass

CODING AND STANDARDS

Codes

36465, 36466, 36470, 36471, 36473, 36474, 36475, 36476, 36478, 36479, 36482, 36483, 37700, 37718, 37722, 37735, 37760, 37761, 37765, 37766, 37780, 37785

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- Varicose veins: are abnormally dilated veins virtually always in the lower extremities, lower abdominal wall or pelvic region. They can be asymptomatic, cause cosmetic embarrassment, or may be symptomatic with a sense of discomfort, pressure, itching and heaviness.
- Venous reflux: is retrograde flow due to valvular incompetence
- Axial reflux: is defined as uninterrupted reflux from the junction of a truncal vein and the appropriate deep vein and extending distally at least to the knee or ankle
- Truncal veins are the great, small, anterior saphenous, and posterior accessory saphenous veins
- Perforating veins connect the deep and superficial system of veins
- Thermal ablation: involves heat which is usually supplied by laser or radiofrequency applied to metal probes
- Nonthermal ablation implies ablation by any means other than thermal
- Conservative measures for treating varicose veins: include compression, ambulation, limb elevation, and avoiding prolonged sitting and standing

Venous Clinical Severity Score (VCSS) ⁽¹⁰⁾

Pain/Discomfort	None: 0	Mild: 1	Moderate: 2	Severe: 3
e.g., aching, fatigue, soreness, heaviness, burning		Occasional pain that does not restrict daily activities	Daily pain may interfere with regular daily activities (does not prevent)	Daily pain limiting most regular daily activities

Varicose Veins	None: 0	Mild: 1	Moderate: 2	Severe: 3
≥ 3 mm (diameter) in standing position		Few: scattered (varicosities confined to branch veins or clusters) Includes corona phlebectatica (ankle flare)	Multiple varicosities confined to the calf or the thigh	Multiple varicosities involves calf and thigh

Venous Edema	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin		Edema limited to the foot and ankle	Edema extends above the ankle but below the knee	Edema extends to the knee and above

Skin Pigmentation	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin Does not include focal pigmentation over varicose veins or due to other chronic diseases (e.g., vasculitis purpura)		Pigmentation is limited to perimalleolar area	Diffuse pigmentation that involves lower third of the calf	Wider distribution pigmentation above the lower third of the calf

Inflammation	None: 0	Mild: 1	Moderate: 2	Severe: 3
More than recent pigmentation (i.e., erythema, cellulitis, venous eczema, dermatitis)		Inflammation limited to perimalleolar area	Diffuse inflammation over lower third of calf	Wider distribution inflammation above lower third of calf

Induration	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin of secondary skin & subcutaneous changes (e.g., chronic edema with fibrosis, hypodermatitis); includes white atrophy & Lipodermatosclerosis		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of calf

Active Ulcer Number	0	1	2	≥ 3
Active Ulcer Duration (longest active)	N/A	< 3 months	> 3 months but < 1 y	Not healed for > 1 y
Active Ulcer Size (largest active)	N/A	< 2 cm (diameter)	2-6 cm (diameter)	>6 cm (diameter)

Compression Therapy Use	0	1	2	3
	Not Used	Intermittent stocking use	Stocking use most days	Stocking use full compliance

CEAP Classification (Clinical Class, Etiology, Anatomy, Pathology) ⁽¹¹⁾

CEAP categories; Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)

Clinical (C) Classifications (C Classes present in Limb)

- C₀ – No visible or palpable signs of venous disease
- C₁ – Telangiectasias or reticular veins (< 3mm)
- C₂ – Simple varicose veins (≥ 3mm diameter)
 - C_{2r} – Recurrent varicose veins
- C₃ – Ankle edema of venous origin (not foot edema)
- C₄ – Changes in skin and subcutaneous tissue secondary to CVD
 - C_{4a} – Pigmentation or eczema
 - C_{4b} – Lipodermatosclerosis or atrophie blanche
 - C_{4c} – Corona phlebectatica
- C₅ – Healed venous ulcer
- C₆ – Open venous ulcer
 - C_{6r} – Recurrent active venous ulcer

Subscripts of C Classes Indicating presence or absence of symptoms

- **S - Symptomatic**
 - Ache
 - Pain

- Tightness
- Skin irritation
- Heaviness
- Muscle cramps
- Other complaints attributable to venous dysfunction

- **A – Asymptomatic**

Etiologic (E) Classification

- E_c – Congenital
- E_p – Primary
- E_s – Secondary
 - E_{si} – Secondary – intravenous
 - E_{se} – Secondary – extravenous
- E_n – No cause identified

Anatomic (A) Classification

- A_s – Superficial veins
 - Telangiectasia
 - Reticular Veins
 - Great saphenous vein above knee
 - Great saphenous vein below knee
 - Small saphenous vein
 - Anterior accessory saphenous vein
 - Nonsaphenous vein
- A_p – Perforator veins
 - Thigh perforator vein
 - Calf perforator vein
- A_d – Deep veins
 - Inferior vena cava
 - Common iliac vein
 - Internal iliac vein
 - External iliac vein
 - Pelvic veins
 - Common femoral vein

- Deep femoral vein
- Femoral vein
- Popliteal vein
- Crural (tibial) vein
- Peroneal vein
- Anterior tibial vein
- Posterior tibial vein
- Muscular veins
- Gastrocnemius vein
- Soleal vein
- A_n – No venous anatomic location identified

Pathophysiologic (P) Classification

- P_r – Reflux
- P_o – Obstruction
- P_{r,o} – Reflux and obstruction
- P_n – No venous pathophysiology

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AASV: Anterior accessory saphenous vein (now known as the anterior saphenous vein)

AUC: Appropriate Use Criteria (Scores)

CEAP: Clinical (C), Etiology (e), Anatomical (A), and Pathophysiological (P)

PCF: Physician compounded foam

SAP: Stab avulsion phlebectomy

r-VCSS: Revised Venous Clinical Severity Score

SUMMARY OF EVIDENCE

European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs ⁽⁶⁾

Study Design: This document is a clinical practice guideline by the European Society for Vascular Surgery (ESVS) on the management of chronic venous disease (CVD) of the lower limbs. It includes recommendations based on systematic literature reviews and expert consensus.

Target Population: Patients with chronic venous disease of the lower limbs, including those with superficial, perforating, and deep vein pathologies.

Key Factors:

Epidemiology: The document provides prevalence data for different CEAP classes of CVD and discusses risk factors such as female gender, age, obesity, prolonged standing, positive family history, and parity.

Anatomy: Detailed descriptions of the superficial, perforating, and deep veins of the lower limbs.

Pathophysiology: Discusses the inflammatory phenomena leading to venous wall and valve changes, venous hypertension, and subsequent skin changes.

Clinical Presentation: Symptoms include heaviness, tired legs, itching, nocturnal cramps, burning pain, and venous claudication.

Investigations: Recommendations for duplex ultrasound, abdominal ultrasound, cross-sectional imaging, and intravascular ultrasound.

Management: Conservative management options such as physical methods, compression therapy, and pharmacological treatment. Interventional treatments for superficial venous incompetence, including thermal and non-thermal ablation techniques.

The 2022 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part 1 ⁽⁷⁾

Study Design: This document is part I of the clinical practice guidelines by the Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society for the management of varicose veins of the lower extremities. It includes evidence-based recommendations based on systematic reviews and meta-analyses.

Target Population: Patients with varicose veins of the lower extremities, including those with CEAP class 2 varicose veins.

Key Factors:

Duplex Ultrasound: Recommendations for using duplex ultrasound scanning as the diagnostic test of choice to evaluate venous reflux.

Treatment Options: Comparison of open surgical treatment (ligation and stripping) vs endovenous ablation techniques, thermal vs non-thermal ablation, and management of incompetent perforating veins.

Concomitant Treatment: Recommendations on the concomitant vs staged treatment of varicose tributaries using phlebectomy or sclerotherapy.

The 2023 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part II ⁽⁹⁾

Study Design: This document is part II of the clinical practice guidelines by the Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society for the management of varicose veins of the lower extremities. It includes evidence-based recommendations based on systematic reviews and meta-analyses.

Target Population: Patients with varicose veins of the lower extremities, including those with CEAP class 2 varicose veins.

Key Factors:

Compression Therapy: Recommendations for the use of compression therapy vs intervention and post-procedure compression therapy.

Pharmacological Treatment: Recommendations for the use of venoactive drugs and nutritional supplements for symptomatic patients.

Evaluation and Treatment: Guidelines for the evaluation and treatment of varicose tributaries, management of superficial venous aneurysms, and management of complications such as thrombosis and bleeding.

ANALYSIS OF EVIDENCE

Key Points of Agreement ^(6,7,9)

1. **Duplex Ultrasound Scanning:** All articles agree on its importance for diagnosing venous reflux.
2. **Endovenous Ablation:** Preferred over traditional surgical methods due to better patient outcomes and quicker recovery.
3. **Compression Therapy:** Recommended as an initial treatment, especially for less severe cases.

While there is a consensus on the importance of duplex ultrasound scanning and the effectiveness of endovenous ablation techniques, the guidelines differ in their emphasis on pharmacological treatments, ethical considerations, and the management of complications. These differences highlight the evolving nature of varicose vein treatment and the need for personalized approaches based on individual patient needs and clinical judgment.

POLICY HISTORY

Date	Summary
December 2025	<ul style="list-style-type: none"> Codes within the Coding section were edited to reflect changes made by the American Medical Association. Deleted: 37500
June 2025	<ul style="list-style-type: none"> Added third bullet to general information Added medical adhesive as a General treatment method Added Summary of Evidence and Analysis of Evidence
January 2025	<ul style="list-style-type: none"> This guideline replaces UM 1252 Endovascular Venous Laser-Radiofrequency Ablation This guideline replaces UM 1253 Lower Extremity Venous Ligation/Stripping This guideline replaces UM 1254 Lower Extremity Venous Sclerotherapy This guideline replaces UM 1255 Lower Extremity Venous Stab Phlebectomy

LEGAL AND COMPLIANCE

Guideline Approval

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7291 for Enhanced External Counter Pulsation

Guideline Number: Evolent_CG_7291	<u>Applicable Codes</u>	
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Original Date: July 2011	Last Revised Date: July 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Enhanced External Counter Pulsation (EECP).

Special Note

- To review a request for medical necessity, the following items must be submitted for review:
 - Progress note that prompted request (including list of current medications)
 - Records from last EECP treatment (if applicable)
 - Most recent Echocardiogram, Stress test
 - Most recent cardiac catheterization report

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR ENHANCED EXTERNAL COUNTER PULSATION

An initial treatment course of 35 one-hour sessions, given 5 days per week will be considered for:

- Patients with chronic coronary disease, refractory angina pectoris, or with Class III or IV angina symptoms per New York Heart Association (NYHA) or Canadian Cardiovascular Society (CCS) and on maximally tolerated guideline-directed medical therapy (GDMT)^(6,7)
- Patients who are not amenable for revascularization either percutaneously Percutaneous Coronary Intervention (PCI) or surgically coronary artery bypass graft (CABG) due to ⁽⁶⁾:
 - Inoperative condition or high risk of operative complications or post-op failure
 - Recurrent angina pectoris despite multiple revascularization procedures
 - Unsuitable coronary anatomy
 - Additional co-morbid states which could create excessive risk
- Repeat courses of EECP will be considered on a case-by-case basis for patients with refractory angina pectoris if all the following criteria are met ⁽⁶⁾
 - Patients meets medical necessity criteria for EECP **AND**
 - Prior EECP has resulted in a sustained improvement in symptoms, with a significant (greater than 25%) reduction in frequency of angina symptoms with:
 - Improvement by one or more angina classes (NYHA or CCS) **AND**
 - Three or more months has elapsed from the prior EECP treatment

CONTRAINDICATIONS OF ENHANCED EXTERNAL COUNTER PULSATION ^(6,7)

- Decompensated heart failure
- Severe Aortic Regurgitation
- Severe Peripheral Artery Disease
- Recent myocardial infarction within the last 3 months
- Recent surgical intervention within the last 6 weeks
- Recent cardiac catheterization (1-2 weeks) or arterial femoral puncture
- Unstable angina pectoris
- Severe hypertension > 180/110 mm Hg
- Heart rate of <35 or >125 beats per minute

- Arrhythmias that interfere with EECPP triggering
- Severe venous disease (thrombophlebitis, deep vein thrombosis, or pulmonary embolism)
- Severe lower extremity vaso-occlusive disease
- Presence of a documented aortic aneurysm requiring surgical repair
- Pregnancy

CODING AND STANDARDS

Codes

G0166, I20.0, I20.1, I20.2, I20.8, I20.81, I20.89, I20.9, I25.10, I25.110, I25.111, I25.112, I25.118, I25.119, I25.6, I25.700, I25.701, I25.702, I25.708, I25.709, I25.710, I25.711, I25.712, I25.718, I25.719, I25.720, I25.721, I25.722, I25.728, I25.729, I25.730, I25.731, I25.732, I25.738, I25.739, I25.750, I25.751, I25.752, I25.758, I25.759, I25.760, I25.761, I25.762, I25.768, I25.769, I25.790, I25.791, I25.792, I25.798, I25.799, I25.810, I25.811, I25.812, I25.82, I25.85, I25.89, I25.9

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Enhanced External Counter pulsation is a nonsurgical outpatient treatment of angina pectoris and coronary artery disease (CAD) refractory to medical and/or surgical therapy. This therapy increases blood flow to the heart by compressing blood vessels in the lower extremities. The patient is placed on a treatment table where their lower trunk and lower extremities are wrapped in a series of three compressive air cuffs which inflate and deflate in synchronization with the patient's cardiac cycle.

Although EECF devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Non-coverage of hydraulic versions of these types of devices remains in force.

New York Heart Association Grading Scale for Heart Failure ⁽⁸⁾

- Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath)
- Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or chest pain
- Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or chest pain
- Class IV: Symptoms of heart failure at rest. Any physical activity causes further discomfort

Canadian Cardiovascular Society Grading Scale for Angina ⁽⁹⁾

- Class I: Ordinary physical activity does not cause angina, such as walking or climbing stairs. Angina occurs with strenuous, rapid or prolonged exertion
- Class II: Slight limitation of ordinary activity. Angina occurs only during vigorous physical activity, such as walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals in cold, wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions
- Class III: Marked limitation of ordinary physical activity. It is induced by walking one or two-level blocks and climbing one flight of stairs in normal conditions and at a normal pace
- Class IV: Inability to carry on any physical activity without discomfort. Anginal syndrome may be present at rest

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AUC: appropriate use criteria

CABG: Coronary Artery Bypass Graft

CAD: Coronary Artery Disease

CCS: Canadian Cardiovascular Society

EECP: Enhanced External Counter Pulsation

FDA: Food and Drug Administration

GDMT: Guideline-Directed Medical Therapy

NYHA: New York Heart Association

PCI: Percutaneous Coronary Intervention

SUMMARY OF EVIDENCE

Enhanced external counterpulsation: A unique treatment for the “No-Option” refractory angina patient ⁽⁶⁾

Study design: Involved a literature review to evaluate the safety and efficacy of EECP in patients with RAP.

Target population: Patients with symptomatic coronary artery disease (CAD) who have not responded to standard revascularization procedures and aggressive pharmacotherapy. These patients typically have advanced CAD with recurrent angina pectoris not amenable to revascularization due to unsuitable coronary anatomy, multiple previous revascularization attempts, age, additional comorbid conditions, or patient preference.

Key factors: The review involved a sweeping search and analysis of existing published literature on EECP. The review found that EECP consistently reduces angina pectoris, extends time to exercise-induced ischemia, decreases dependency on nitroglycerine for frequent chest pain, increases maximum workload, and improves the quality of life in patients with symptomatic stable angina. EECP was also found to be well-tolerated by the vast majority of patients, with relatively few adverse events reported. The study suggests that EECP is a safe and likely the best available method of treatment for patients presenting with symptomatic CAD not amenable to further revascularization.

2014 ACC/AHA/AATS/PCNA/SCAI/STS Focused Update of the Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease ⁽⁷⁾

Study design: A comprehensive review of late-breaking clinical trials and other selected data presented at major scientific meetings and published through October 2013.

Target population: Adult patients with stable known or suspected ischemic heart disease, including those with new-onset chest pain or stable pain syndromes. The guidelines also apply to patients with ischemic equivalents, such as dyspnea or arm pain with exertion, and those who have become asymptomatic with appropriate therapy.

Key factors: The guidelines emphasize the use of coronary angiography for patients with presumed SIHD who have unacceptable ischemic symptoms despite guideline-directed medical therapy (GDMT) and are candidates for revascularization. Noninvasive stress testing is recommended as the initial study for most patients with suspected SIHD. The guidelines recommend GDMT for all patients with SIHD. Additional therapies, such as chelation therapy and enhanced external counterpulsation (EECP), are discussed for specific patient populations. The guidelines also address the use of coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) for revascularization in patients with multivessel coronary artery disease (CAD) and diabetes mellitus. The guidelines include recommendations for the management of SIHD in special subgroups, such as women, older adults, and persons with chronic kidney disease. The importance of a Heart Team approach for decision-making in patients with complex multivessel CAD and diabetes mellitus is emphasized

ANALYSIS OF EVIDENCE

Analysis ^(6,7):

Both articles support the use of EECP as a safe and effective treatment for patients with RAP. They share conclusions on the benefits of EECP in reducing angina, improving exercise tolerance, decreasing nitroglycerine dependency, and enhancing quality of life.

Shared Conclusions:

Both articles highlight the benefits of EECP in improving symptoms and quality of life for patients with RAP:

- Both articles agree that EECP consistently reduces angina pectoris.
- EECP extends the time to exercise-induced ischemia and increases maximum workload.
- EECP decreases dependency on nitroglycerine for frequent chest pain.
- Both articles emphasize that EECP improves the quality of life in patients with symptomatic stable angina.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none"> • No substantial clinical content changes • Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices • Applicable Line of Business adjusted – Medicare checked • Added in ICD-10 codes applicable to the guideline • Added a Summary of Evidence and Analysis of Evidence

Date	Summary
November 2024	<ul style="list-style-type: none"> This guideline replaces UM Cardio 1117 Enhanced External Counter Pulsation (EECP)

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7292 for Infrainguinal Open Arterial Vascular Surgery

Guideline Number: Evolent_CG_7292	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for infrainguinal open arterial bypass surgery.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

General Considerations

For this policy procedures will be considered if they involve the common, deep (profunda), superficial femoral, or popliteal arteries. Arteries below the popliteal artery may be referred to as “infrapopliteal” and include the tibioperoneal trunk, anterior tibial, posterior tibial, peroneal, plantar, dorsalis pedis, and tarsal arteries.

INDICATIONS

Claudication ^(6,7)

When **ALL** the following requirements have been met (**AUC Score 6**):

- Impairment of activities of daily living and/or work
- Absence of other conditions that would limit exercise even if claudication is improved (e.g. arthritis, angina, chronic respiratory disease)
- Member is on guideline directed medical therapy (GDMT)
- Inadequate response to a supervised or structured exercise program for 12 weeks
- Proximal clinically significant aortoiliac disease is not present, or successfully treated such that it is unlikely to be responsible for ongoing claudication.
 - If still present and clinically significant it will be treated concurrently with the infrainguinal procedure by open or endovascular techniques
- A resting Ankle Brachial Index (ABI) of abnormal (≤ 0.9) or noncompressible (> 1.4) or either:
 - TBI < 0.7
 - $\geq 20\%$ reduction in ankle pressure on exercise testing.

NOTE: If arteries are noncompressible (ABI > 1.4), making these tests unreliable, abnormal Doppler tracings or pulse volume recordings (PVR) can be provided

- An anatomically suitable lesion with imaging demonstrating one of the following:
 - $\geq 70\%$ stenosis (Bailey et al 2019) on angiography (CTA, MRA, invasive angiography)
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥ 300 cm/s or PSV ratio ≥ 4.0 and with monophasic flow pattern
- A duplex scan of the ipsilateral great saphenous vein has been performed to evaluate suitability for use as a bypass graft (unless contraindicated or unavailable, the contralateral vein should be evaluated if the ipsilateral vein is absent or unusable. If bypass to a tibial artery is contemplated and leg vein is not available, arm vein should be evaluated) ⁽⁸⁾

Chronic Limb Threatening Ischemia (CLTI) ^(6–8)

When the following requirements have been met (**AUC Score 8**):

- Gangrene or nonhealing ischemic wounds present for more than 2 weeks despite provider directed and described wound care **OR** wound Grade 1-3 based on the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wiffl). One of the following must be present:
 - An ABI < 0.8
 - Ankle pressure < 100 mmHg
 - Toe pressures or TCPO₂ < 60 mmHg
 - If ABI ≥ 1.4 , then one of the following :

- Toe pressures or TCPO₂ < 60 mmHg
 - TBI < 0.7 with Monophasic PVR or Doppler waveforms
- If no Gangrene or non-healing wounds but Rest Pain, then with **ANY** of the following:
 - An ABI < 0.4
 - If ankle pressures unrecordable, Toe pressure or TcPO₂ < 30 mmHg
 - PVR amplitude or Doppler waveforms showing flat line or < 5mm with absent diastolic notch
- An anatomically suitable lesion with imaging demonstrating at least one of the following:
 - ≥50% stenosis, as shown by CTA, MRA, or invasive angiography
 - Duplex ultrasound with absent velocities **OR** peak systolic velocity (PSV) ≥250 cm/s **AND** PSV ratio of ≥2.0 across the stenosis with monophasic distal flow
- A duplex scan of the ipsilateral great saphenous vein has been performed to evaluate suitability for use as a bypass graft (unless contraindicated or unavailable, the contralateral vein should be evaluated if the ipsilateral vein is absent or unusable. If bypass to a tibial artery is contemplated and leg vein is not available, arm vein should be evaluated)
- If a graft material other than autogenous vein will be used, the reason(s) for choosing that graft must be described in the notes provided since vein is the conduit of choice especially for bypass to the below knee popliteal or infrapopliteal arteries (see **Definitions**).

Other Indications or Specific Open Vascular Procedures ^(8,9)

- For the treatment of femoral-popliteal aneurysms with **ANY** of the following:
 - ≥ 20mm
 - < 20mm with extensive thrombus (≥50% lumen involvement) and at least one of the following:
 - Evidence of distal embolization
 - Poor distal runoff

NOTE: If a graft other than vein will be used, the reason(s) for that choice must be described in the notes provided since vein is the conduit of choice especially for bypass to the below knee popliteal or tibial arteries.
- To allow local podiatric or orthopedic interventions when circulation may be tenuous but in and of itself not severe enough to warrant intervention; with **ANY** of the following :
 - An ABI < 0.8.
 - Ankle pressure < 100mmHg
 - Toe Pressure or TcPO₂ < 60mmHg
 - If ABI ≥1.4 then one of the following :

- Toe Pressure or TcPO₂ < 60mmHg
- Monophasic PVR or Doppler waveforms
- Common femoral endarterectomy to treat claudication or CLTI will follow the same policies listed above (but preoperative evaluation of the saphenous vein is not a requirement since often prosthetic patch is use instead). Common femoral endarterectomy can be performed as a standalone procedure.
- A patch (synthetic or vein) used as an add-on procedure where the provider places the patch (also known as a cuff) to the distal end of the graft to help maintain patency
- A patch (synthetic or vein) used for the treatment of stenosis within a vein bypass graft in a symptomatic or asymptomatic member with concern for impending graft failure and **ANY** one of the following ^(10,11):
 - Peak Systolic Velocity (PSV) of ≥ 180 cm/s
 - A velocity ratio of ≥ 2.0
 - An end diastolic velocity of < 45 cm/s
- Embolectomy or Thrombectomy performed for acute ischemia

Limitations

- If a bypass is being requested for claudication there can be no assertion, directly or indirectly, that treatment is required to prevent imminent amputation.
- Femoral-tibial artery bypass with prosthetic or non-autogenous graft material should only be used if ALL possible autologous vein is not available and an endovascular alternative is not feasible or has been unsuccessful.
- Common femoral endarterectomy cannot be requested concurrently with a bypass unless it involves the contralateral limb.

CODING AND STANDARDS

Codes

35302, 35303, 35304, 35306, 35351, 35355, 35361, 35363, 35371, 35372, 35539, 35540, 35556, 35558, 35560, 35563, 35565, 35566, 35570, 35571, 35572, 35583, 35585, 35587, 35646, 35647, 35650, 35654, 35656, 35661, 35663, 35665, 35666, 35671, 35681, 35682, 35683, 35685, 35700, 35701, 35702, 35703, 35721, 35741, 35860, 35879, 35881, 35883, 35884, 35903

Applicable Lines of Business

☒	CHIP (Children's Health Insurance Program)
☒	Commercial

<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- An **anatomically suitable lesion** is one where the appropriate intervention would have low risk, and a high probability of initial and long-term success based on accepted lesion classifications such as TASC II or GLASS. ⁽⁶⁾
- **Ankle Brachial Index (ABI)** is measured by dividing the highest brachial blood pressure in either arm by the highest pressure obtained from the dorsalis pedis or posterior tibial artery.
- **Chronic Limb Threatening Ischemia (CLTI)** has replaced **Critical Limb Ischemia (CLI)** since the threat to limb viability in patients with PAD is not only related to ischemia but other factors such as infection, neuropathy, and general patient morbidities. Further, “critical” implies that treatment is urgent to avoid limb loss, while some patients can keep their legs for extended periods of time even in the absence of revascularization. CLTI is defined clinically by the presence of Rest Pain, gangrene, a nonhealing wound or ulceration lasting more than 2 weeks despite appropriate wound care. Infection may make invasive treatment more urgent. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wiffl) is helpful in defining CLTI and prognosticating indications for treatment and outcome. ⁽⁹⁾
- **Claudication** is a symptom complex of pain that begins with ambulation and that is relieved within a brief time by walking cessation. It is described by the intensity of discomfort, the distance walked, the duration of the walk and the impact that it has on quality of life (QOL) and activities of daily living (ADL). Claudication does not occur at rest. If left untreated, the natural history of claudication is slow progression, yet amputation is rare occurring in less than 5% of patients.
- **Clinically significant disease** is such that it is likely causing ischemic symptoms or findings
- **Endovascular intervention** is the treatment of peripheral arterial disease with angioplasty, atherectomy, intravascular lithotripsy, or stents. It is performed by opening the blood vessel with a device placed on a catheter inserted through a blood vessel. In some cases, drug elution is added to the device to prevent restenosis. Intravascular ultrasound and filters may assist the procedure. In some circumstances mechanical thrombectomy or drug infusion thrombolysis may be required.
- **Guideline Directed Medical Therapy (GDMT)** includes recommendations for antiplatelet therapy, cilostazol (unless contraindicated or not tolerated), statins, glycemic

and hypertension control, structured exercise program, smoking cessation including planning, counseling, or behavior modification and pharmacotherapy if needed. Duration should be for at least 12 weeks.

- **Physiologic studies** include ABI, TBI, Toe pressures, TCPO₂, PVR or Doppler tracings
- **Rest Pain** is a distinct pain syndrome lasting more than 2 weeks, implying CLTI. It is defined as pain in the foot or toes aggravated by elevation and relieved by dependency. Nocturnal pain is not necessarily Rest Pain since there are other causes of pain at night. Rest pain does not usually imply the same urgency for treatment as gangrene or nonhealing wounds.
- **Structured exercise program** is provider-directed and monitored. It involves walking to a pain threshold 3 times a week.
- **Toe Brachial Index** is measured by dividing the highest brachial arm pressure by the pressure obtained from the First toe by any method. Unlike the ABI, the toe pressures are usually not affected by arterial calcification.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ABI: Ankle Brachial Index

AR: Authorization Request

AUC: Appropriate use criteria

CLTI: Chronic limb Threatening ischemia

CPT: Current Procedural Terminology

CTA: Computed Tomography Angiography

DSA: Digital Subtraction Angiography

GDMT: Guideline directed medical therapy

GLASS: Global Anatomic Staging System

PAD: Peripheral artery disease

PSV: Peak Systolic Velocity

PTA: Percutaneous transluminal angioplasty

PVR: Pulse Volume Recording

TASC: Trans-Atlantic Inter-Society Consensus

TBI: Toe Brachial Index

WIFI Classification: Wound, Ischemia, and Foot Infection

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

SUMMARY OF EVIDENCE

ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention⁽⁶⁾

Study Design: This study involved the development of Appropriate Use Criteria (AUC) for peripheral artery intervention (PAI). The process included drafting patient scenarios, assumptions, and definitions based on published guidelines, trial data, and expert opinions. The scenarios were evaluated by an independent rating panel using a scoring scale from 1 to 9.

Target Population: The study focused on patients with peripheral artery disease (PAD) who may require revascularization treatments. This includes patients with renal artery stenosis, lower extremity disease, critical limb ischemia, asymptomatic artery disease, and secondary treatment options for lower extremity disease.

Key Factors:

Clinical Scenarios: 45 clinical scenarios with up to 6 intervention options per scenario were developed and categorized into 6 general sections.

Scoring: Each indication was scored as “Appropriate” (7 to 9), “May Be Appropriate” (4 to 6), or “Rarely Appropriate” (1 to 3).

Emphasis: Adherence to medical therapy was emphasized, with revascularization considered when medical therapy is insufficient.

Endovascular and Surgical Approaches: Both approaches were deemed appropriate in scenarios involving tissue loss or end organ compromise, with a tendency to select endovascular approaches.

2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease⁽⁷⁾

Study Design: This document is the 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease. It was developed by the American College of

Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines in collaboration with several other organizations.

Target Population: The guidelines are intended for clinicians treating patients with lower extremity peripheral artery disease across its multiple clinical presentation subsets, including asymptomatic PAD, chronic symptomatic PAD, chronic limb-threatening ischemia, and acute limb ischemia.

Key Factors: The document provides comprehensive recommendations on the clinical assessment, diagnostic testing, medical therapy, preventive foot care, exercise therapy, revascularization techniques, management of chronic limb-threatening ischemia, and acute limb ischemia. It also addresses special considerations such as risk amplifiers, health disparities, and management of PAD in older patients.

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (Wifl) ⁽⁹⁾

Study Design: This document introduces the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System, known as Wifl (Wound, Ischemia, and foot Infection).

Target Population: The classification system is designed for patients with threatened lower extremities due to chronic ischemia, particularly those with diabetes and diabetic foot ulcers.

Key Factors: The Wifl system stratifies patients based on the severity of wounds, ischemia, and infection. It aims to provide a more precise description of disease burden and improve outcomes analysis for various therapies. The system includes four grades for each factor and uses a Delphi consensus process to estimate the risk of amputation and the benefit of revascularization.

ANALYSIS OF EVIDENCE

Shared Conclusions

1. **Importance of Revascularization:** All three articles emphasize the critical role of revascularization in managing peripheral artery disease (PAD) and critical limb ischemia (CLI). They agree that revascularization, whether through open surgical or endovascular procedures, is essential for improving limb salvage and patient outcomes.
2. **Risk Stratification:** The articles highlight the importance of risk stratification in determining the appropriate treatment approach. They all agree that patient-specific factors, such as the severity of ischemia, wound extent, and presence of infection, should guide the choice of revascularization strategy.
3. **Multidisciplinary Approach:** The need for a multidisciplinary approach to managing PAD and CLI is a common theme. The articles stress the importance of collaboration among vascular surgeons, interventional radiologists, podiatrists, and other specialists to optimize patient care.

In summary, while all three articles agree on the importance of revascularization, risk stratification, and a multidisciplinary approach, they differ in their specific criteria for revascularization, focus on patient populations, and recommendations for specific procedures.

These differences highlight the need for individualized treatment plans based on patient-specific factors and the importance of a comprehensive approach to managing PAD and CLI.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> • Updated citations • Added AUC scores • Added third bullet to General Information • Added Summary of Evidence and Analysis of Evidence
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1164 for Femoral Popliteal Bypass Surgery • Guideline name changed to Infrainguinal Open Arterial Vascular Surgery • Added CPT code 35685 • Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolut Clinical Guideline 7299 for Hemodialysis Access Creation

Guideline Number: Evolent_CG_7299	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Hemodialysis Access Creation.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

General Considerations

- Hemodialysis access can be achieved via a central venous catheter (CVC) or via creation of an arteriovenous fistula (AVF) or arteriovenous graft (AVG). For the most part, CVC(s) should be regarded as temporary procedures and avoided whenever possible. Except in rare circumstances a CVC should always be tunneled (CVTC) (see **Definitions**).
- If there is sufficient time for permanent access to be created an AVF is generally preferred over an AVG assuming suitable anatomy, local limb conditions and patient preference. The previous “fistula first” initiative is no longer appropriate.
- Providers must involve patients in a shared decision-making process involving reason(s)

for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided.

INDICATIONS ⁽⁶⁾

Central Venous Catheters

- Short Term indications include ANY of the following:
 - An AVF or AVG has been created but is not ready for use
 - Acute indication for hemodialysis such as acute transplant rejection
 - Peritoneal dialysis patients requiring a time limited period of rest or resolution of a complication.
 - Complications of an AVF or AVG that result in temporary non-use until the problem is resolved
 - Living donor confirmed within the next 90 days but dialysis required in the interim
- Long term indications include ANY of the following:
 - Multiple prior failed arteriovenous (AV) accesses with no available options
 - Limited life expectancy
 - Valid patient preference whereby use of an AV access will severely limit quality of life or achievement of life goals, and after the patient has been properly informed of patient specific risks and benefits of other potential and reasonable access options for that patient (if available)
 - Absence of an AV access creation option due to severe arterial inflow disease or outflow venous obstruction, or adverse local limb conditions
 - Diminutive patients or children with prohibitively small vessels

AV Fistula or AV Graft

- Dialysis-dependent renal failure expected to be of long-term duration

Limitations

- A CVC should not be inserted if dialysis can be delayed long enough for a functional AVF or AVG to be created
- An AVF should not be created in a terminally ill patient with life expectancy of less than 6 months unless specifically requested by the patient

CODING AND STANDARDS

Codes

36005, 36010, 36011, 36800, 36810, 36815, 36818, 36819, 36820, 36821, 36825, 36830, 36835, 36836, 36837, 75820, 75822

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Hemodialysis is a process of purifying the blood of a person whose kidneys are not working normally (renal failure). Hemodialysis requires vascular access to obtain blood for purifying in the dialysis machine and then to return blood to the body. This can be achieved via a centrally placed venous catheter (CVC) or an arteriovenous (AV) fistula (AVF) or AV graft. CVCs are preferably tunneled from the insertion site to another site from which it is inserted into a central vein (central vein tunneled catheter (CVTC))

An **arteriovenous fistula (AV fistula)** is a surgical or endovenous (minimally invasive radiologic) procedure where a vein is connected to an artery. This artificial connection allows the vein to become larger and for the walls of the vein to thicken, a process termed maturation. A mature fistula makes it easier for the vein to be punctured repeatedly for dialysis. Maturation typically takes three to six months to occur. An arteriovenous fistula is the preferred type of vascular access due to lower rate of infection and clot formation, resulting in greater longevity than other types of vascular access. However, not everyone is a good candidate for an arteriovenous fistula, particularly older patients, and patients with small veins.

An **AV Graft** is considered if the patient is not a suitable candidate for an AVF. An arteriovenous graft is an artificial tubing that is surgically attached on one end to an artery, and on the other end to a vein. The tube is placed entirely under the skin. AVG are more prone to infection and clotting than AVF.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms

AV: Arteriovenous

AVF: Arteriovenous fistula

AVG: Arteriovenous graft

CPT: Customary Procedural Terminology

CVC: Central venous catheter

CVTC: Central venous tunneled catheter

PTFE: Polytetrafluoroethylene

SUMMARY OF EVIDENCE

KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update ⁽⁶⁾

Study Design: The guideline update was conducted by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI). The update involved a comprehensive review of the literature, including more than 4,600 articles, of which 286 were included in the evidence tables used to develop the 26 guideline sections. The evidence review was independently conducted using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.

Target Population: The guidelines are intended for multidisciplinary practitioners who care for chronic kidney disease (CKD) patients and their vascular access. This includes nephrologists, surgeons, interventional radiologists, nurses, and other healthcare professionals involved in the management of hemodialysis vascular access.

Key Factors:

End-Stage Kidney Disease (ESKD) Life-Plan: The guidelines introduce the concept of an individualized ESKD Life-Plan, which maps out a comprehensive strategy for dialysis modalities and vascular access for the lifetime of the patient.

Vascular Access Choice: The guidelines provide recommendations on the choice of vascular access, including arteriovenous fistulas (AVFs), arteriovenous grafts (AVGs), and central venous catheters (CVCs), based on patient circumstances and preferences.

Vascular Access Types and Locations: The guidelines discuss the indications for use, types, and locations of vascular access, emphasizing a patient-centered approach.

Preoperative and Postoperative Care: The guidelines include recommendations for preoperative vessel mapping, postoperative evaluation, and interventions to enhance AVF maturation and prevent complications.

Complications and Management: The guidelines address the prevention, monitoring, and treatment of complications related to vascular access, including infections, thrombosis, and stenosis.

ANALYSIS OF EVIDENCE

These guidelines provide a comprehensive framework for managing vascular access in hemodialysis patients, emphasizing a patient-centered approach and the importance of individualized care plans. The evidence-based recommendations aim to improve patient outcomes and reduce complications associated with vascular access. ⁽⁶⁾

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> Added new bullet-point to the General Statement section No clinical changes
January 2025	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1165 for Hemodialysis Access Creation Added CPT codes 36836 and 36837 Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolut Clinical Guideline 7300 for Hemodialysis Access Maintenance

Guideline Number: Evolut_CG_7300	<u>Applicable Codes</u>	
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Original Date: June 2014	Last Revised Date: June 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for hemodialysis maintenance using angiography, endovascular, or open surgical procedures.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

General Considerations

- For this Policy, the specific endovascular (e.g. angioplasty or stent) or surgical methods (e.g. interposition graft, transposition, or Distal Revascularization and Interval Ligation DRIL procedure) that may be utilized should not be considered when determining whether a procedure can be approved or denied
- Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided.

INDICATIONS FOR DIAGNOSTIC FISTULOGRAM (6,7)

Includes any of the following:

- **ANY** change in physical examination of the dialysis access or limb such as:
 - Decreased or absent thrill or bruit
 - Increased pulsatility
 - Ipsilateral limb swelling
 - Development of new superficial collateral venous channels consistent with venous outflow stenosis or obstruction
 - Distal steal syndrome
 - Ischemic monomelic neuropathy
 - Aneurysm(s) or pseudoaneurysm(s)
 - Clinical evidence of high flow e.g. high output cardiac failure
- **ANY** abnormality encountered during dialysis such as:
 - Arteriovenous access (AV) access thrombosis
 - Aspiration of clots
 - Persistent or new difficulty in cannulation
 - Elevated venous pressures recorded during hemodialysis (static and dynamic pressures) or measured within the vascular access during a diagnostic study (static pressures)
 - Increased bleeding from the needle puncture sites, usually for 3 consecutive dialysis sessions
 - Evidence of decreased flow (Qa)
 - Inadequate dialysis
 - Low Kt/V on a constant dialysis prescription without prolongation of dialysis duration
- **ANY** abnormality encountered by duplex ultrasound such as:
 - Increased pulsatility
 - Decreased flow volume
 - Fistula size <3 mm
 - Severe tortuosity
 - Aneurysm and pseudoaneurysm
 - Depth of the arteriovenous fistula (AVF) or graft (AVG) that would make cannulation difficult

INDICATIONS FOR THERAPEUTIC INTERVENTION ON THE AV ACCESS CIRCUIT ⁽⁶⁾

- **ANY** of the following
 - Autogenous fistulae that have failed to mature after 4 to 6 weeks as expected
 - Symptomatic or complicated aneurysm(s) or pseudoaneurysm(s) (see **Limitations**)
 - AV access infection
 - High flow complications
 - Erosion of the skin overlying the AV access
 - Severe tortuosity or depth of the AV access that would make cannulation difficult
 - **ANY** finding(s) during an indicated diagnostic fistulogram confirming reason(s) for decreased dialysis function, steal, or other access related complication(s), including:
 - Thrombosis
 - Anastomotic stenosis
 - At the arterial anastomosis of an AVF or AVG
 - At the venous anastomosis of an AVG
 - Proximal Inflow arterial stenosis unrelated to the arterial anastomosis
 - Venous outflow stenosis or obstruction distal to the AVF or AVG
 - Intraluminal high-grade stenosis
 - Aberrant veins draining flow away from the main AVF
- Covered intraluminal stents can be utilized to manage AV access aneurysms or pseudoaneurysms but should be reserved for patient contraindications to surgery, lack of a surgical option, or as a temporizing measure for patients with active bleeding
- Symptoms or conditions warranting intervention on aneurysms include any of the following:
 - Pain
 - Access flow dysfunction
 - Thrombus
 - Limited cannulation sites
 - High output congestive heart failure
 - Unacceptable cosmetic disfigurement
 - Rapid enlargement

NOTE: Aneurysm size alone is likely not an indication for treatment in the absence of symptoms of threatened skin.

Limitations ⁽⁶⁾

- A diagnostic fistulogram should not be performed without new clinical findings. Routine fistulogram for “surveillance” is not appropriate
- Preemptive endovascular intervention to improve patency of an AVF or AVG with stenosis, not associated with clinical indicators, is not appropriate

CODING AND STANDARDS

Codes

36831, 36832, 36833, 36901, 36902, 36903, 36904, 36905, 36906, 36907, 36908, 36909, 37607

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions ⁽⁶⁾

- **Interventions on Arteriovenous (AV) dialysis graft/fistula** are intended to restore and/or maintain functional patency of the AV access circuit. However, occasionally interventions may be necessary to move, alter, add to or close the access circuit. Access related procedures encompass endovascular percutaneous or open surgical procedures. They are utilized to treat thrombotic or non-thrombotic flow-related complications or dysfunction, infection, aneurysm, or pseudoaneurysm. In most, but not all cases, a diagnostic fistulogram is performed first. If identified during the fistulogram, culprit lesion(s) should be concurrently treated by an endovascular procedure if appropriate, or soon thereafter by open or hybrid procedures. Open surgical procedures are usually reserved for recurrent stenotic lesions, aneurysms and pseudoaneurysms, AV access infections, steal, ischemic monomelic neuropathy, or difficult access due vein size, tortuosity, or depth.
- **Dialysis access circuit** is the continuing from the heart and the arterial inflow through

the AV access to the venous outflow back to the heart. For coding purposes, the hemodialysis circuit is comprised of a peripheral segment and a central segment. The peripheral segment begins at the arterial anastomosis and extends to the central segment. In the upper extremity the peripheral segment extends up to and includes the axillary vein and entire cephalic vein including the cephalic arch. In the lower extremity, the peripheral segment extends up to and includes the common femoral vein. In the upper extremity, the central segment includes the subclavian and innominate veins through the superior vena cava. In the lower extremity the central segment includes the external iliac and common iliac veins through the inferior vena cava

- **Arteriovenous access** allows for dialysis and includes arteriovenous fistula (AV fistula) or arteriovenous graft (AV graft)
- **Diagnostic Fistulogram** is the diagnostic angiography of the entire AV access circuit from the arterial anastomosis through the central vena cava is performed to identify the area or areas of narrowing or occlusion that are creating flow problems for, or related to, the AV access. It is performed through the AV access or via a remote artery
- **Endovascular fistula (endoAVF)** is an autologous fistula created by endovascular techniques
- **Endovascular interventions** are procedures performed percutaneously utilizing angioplasty, stents, thrombectomy, or thrombolysis. Thrombolysis involves the use of pharmaceuticals that are infused or injected directly into the thrombosed access and which dissolve clot. Mechanical thrombectomy devices may also be utilized to percutaneously remove clots. Thrombectomy can also be performed surgically
- **Open surgical therapy** utilizes direct open access to the conduit and contiguous vessels. Residual vascular stenosis or obstructive lesions are removed and corrected using standard vascular surgical techniques. Angiography is adjunctively employed, when appropriate and medically necessary, to assess the functional integrity of afferent and efferent vessels remote from the surgical field.
- **Vessel superficialization or Transposition** is a procedure where the vessel used for dialysis needs to be moved closer to the surface or away from the neural structures for it to be safely punctured for dialysis
- **DRIL procedure** is a surgical procedure to treat steal and involve distal revascularization and interval ligation of an AV fistula or graft
- **Kt/V** is a number used to quantify hemodialysis treatment (where K = dialyzer clearance of urea, t = dialysis time, and V = volume of distribution of urea approximately equal to the patient's total body water)
- **Failure to mature** an AV fistula that cannot be used successfully for dialysis despite at least 4 weeks of observation since creation, or 6 months despite endovascular or surgical attempts to allow successful cannulation and dialysis
- **Pseudoaneurysm** implies a hole through the vessel or graft with accumulation of flowing blood outside of that vessel but contained by the surrounding tissues.
- **Aneurysm** implies dilatation of all 3 layers of a fistula, vein or artery beyond what would be normally expected following creation of a fistula. Aneurysms can develop anywhere

along the course of the AV access circuit including the inflow artery, but typically occur in the outflow vein. By definition, aneurysms do not occur in grafts, but a ballooning of a collagen biologic graft should still be considered an aneurysm

- **Steal** occurs when creation of an AV access results in distal ischemic complications usually related to decreased distal blood flow. Clinically it presents as a cool extremity with few symptoms, progressing to intermittent symptoms during dialysis, limb claudication, ischemic rest pain and tissue loss. Left untreated Steal can result in limb deformity or amputation.
- **Ischemic monomelic neuropathy** is a poorly understood syndrome that occurs soon after creation of an AV access usually at the elbow. It is diagnosed by acute onset of severe forearm pain, numbness and paresthesia usually without hemodynamic evidence of ischemia and requires immediate ligation of the AV access

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AUC: Appropriate use criteria

AV: Arteriovenous

AVF: Arteriovenous fistula

AVG: Arteriovenous graft

endoAVF: Endovascular arteriovenous fistula

Qa: Intra-access blood flow

SUMMARY OF EVIDENCE

KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update ⁽⁶⁾

Study Design: The guideline update was conducted by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI). The update involved a comprehensive review of the literature, including more than 4,600 articles, of which 286 were included in the evidence tables used to develop the 26 guideline sections. The evidence review was independently conducted using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.

Target Population: The guidelines are intended for multidisciplinary practitioners who care for chronic kidney disease (CKD) patients and their vascular access. This includes nephrologists, surgeons, interventional radiologists, nurses, and other healthcare professionals involved in the management of hemodialysis vascular access.

Key Factors:

End-Stage Kidney Disease (ESKD) Life-Plan: The guidelines introduce the concept of an individualized ESKD Life-Plan, which maps out a comprehensive strategy for dialysis modalities and vascular access for the lifetime of the patient.

Vascular Access Choice: The guidelines provide recommendations on the choice of vascular access, including arteriovenous fistulas (AVFs), arteriovenous grafts (AVGs), and central venous catheters (CVCs), based on patient circumstances and preferences.

Vascular Access Types and Locations: The guidelines discuss the indications for use, types, and locations of vascular access, emphasizing a patient-centered approach.

Preoperative and Postoperative Care: The guidelines include recommendations for preoperative vessel mapping, postoperative evaluation, and interventions to enhance AVF maturation and prevent complications.

Complications and Management: The guidelines address the prevention, monitoring, and treatment of complications related to vascular access, including infections, thrombosis, and stenosis.

ACR Appropriateness Criteria® Dialysis Fistula Malfunction ⁽⁷⁾

Study Design: The study is a rigorous evaluation of dialysis access dysfunction, focusing on arteriovenous access dysfunction, which includes thrombotic flow-related complications, nonthrombotic flow-related complications, and infectious complications. The American College of Radiology Appropriateness Criteria are evidence-based guidelines for specific clinical conditions reviewed annually by a multidisciplinary expert panel. The guideline development and revision process supports the systematic analysis of medical literature from peer-reviewed journals, using established methodology principles such as Grading of Recommendations Assessment, Development, and Evaluation (GRADE) and the RAND/UCLA Appropriateness Method User Manual.

Target Population: The target population includes patients with end-stage renal disease who require dialysis. The study emphasizes the importance of creating and maintaining dialysis access to reduce morbidity, mortality, and treatment costs for these patients. The quality of dialysis is directly dependent on the integrity and reliability of access to the patient's vascular system.

Key Factors:

Dialysis Access Dysfunction: The study categorizes dialysis access dysfunction into three distinct classes: thrombotic flow-related complications, nonthrombotic flow-related complications, and infectious complications. It discusses the restoration of arteriovenous access dysfunction through diagnostic imaging, clinical consultation, percutaneous interventional procedures, surgical management, or a combination of these methods.

Appropriateness Criteria: The American College of Radiology Appropriateness Criteria documents are updated regularly and provide guidelines for determining appropriate imaging examinations for diagnosis and treatment of specified medical conditions. These criteria guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment.

Monitoring and Surveillance: The study highlights the importance of monitoring and surveillance to preempt adverse outcomes and identify lesions within the vascular access before they provoke complications. It suggests the performance of physical examinations, noninvasive and invasive device-based methods, and diagnostic imaging such as Doppler ultrasound or diagnostic fistulography upon detection or suspicion of an access abnormality.

ANALYSIS OF EVIDENCE

Shared Conclusions ^(6,7):

Importance of Diagnostic Imaging: Both articles highlight the critical role of diagnostic imaging in evaluating and managing dialysis access dysfunction.

Endovascular Interventions: Both emphasize the use of PTA and stent placements as primary treatments for stenosis.

Patient-Centered Approach: Both stress the importance of considering individual patient circumstances and preferences in managing dialysis access.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> Added new bullet-point to the General Statement section Added a Summary of Evidence and Analysis of Evidence
January 2025	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1339 for Hemodialysis Access Maintenance Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7302 for Percutaneous Coronary Interventions

Guideline Number: Evolent_CG_7302	<u>Applicable Codes</u>	
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Original Date: January 2026	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

This guideline addresses Percutaneous Coronary Interventions for stable coronary artery disease. **This guideline does NOT cover acute coronary syndromes including ST segment elevation myocardial infarction and non-ST segment elevation myocardial infarction.**

Coronary Artery Stenosis

- The severity of coronary artery stenoses may be defined by either cardiac catheterization or CT Angiography by the following:
 - A diameter stenosis by visual estimation of $\geq 70\%$ for non-left main disease and $\geq 50\%$ for left main disease are considered significant stenoses to guide revascularization.
 - Intermediate coronary stenoses are defined as a diameter stenosis of 40% to 69% and may be candidates for further evaluation to assess the physiologic or anatomic significance.
 - Fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR) can be used to assess physiological lesion significance, with cutoffs of ≤ 0.80 and ≤ 0.89 , respectively.
 - Intravascular ultrasound (IVUS) for left main disease is considered significant for a minimal luminal area $\leq 6.0 \text{ mm}^2$, while a smaller value may be more appropriate in patients of Asian descent ($4.5 - 4.8 \text{ mm}^2$). Lower values are advocated outside of the left main coronary artery.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS FOR PERCUTANEOUS CORONARY INTERVENTION (PCI)

Refractory Angina ⁽⁶⁾

- Patients with stable ischemic heart disease (SIHD), refractory angina (despite medical therapy), and significant coronary artery stenosis in a lesion amenable to PCI

Multivessel Coronary Artery Disease (CAD) ⁽⁶⁾

- Patients with SIHD and the following:
 - Normal ejection fraction
 - Those with abnormal ejection fraction should have documentation why surgical revascularization is not being considered.
 - Significant stenosis in 3 major coronary arteries (with or without proximal LAD)
 - Anatomy is suitable for PCI

Stenosis in Proximal Left Anterior Descending (LAD) artery ⁽⁶⁾

- Patients with SIHD and the following:
 - Normal left ventricular ejection fraction
 - Those with abnormal ejection fraction should have documentation why surgical revascularization is not being considered.
 - Significant stenosis in the proximal LAD

Left Main CAD ⁽⁶⁾

A diameter stenosis by visual estimation of $\geq 50\%$ for left main disease are considered significant stenoses to guide revascularization.

- Selected patients with SIHD and significant left main stenosis in whom PCI can provide equivalent revascularization as CABG

Diabetes Mellitus and Multivessel Coronary Artery Disease (CAD) ⁽⁶⁾

- Patients with Diabetes and multivessel CAD with any of the following:
 - Involvement of the LAD and are not appropriate candidates for coronary artery bypass graft (CABG)
 - Poor candidates for surgery
 - Left main stenosis and low- or intermediate- complexity CAD in rest of the coronary anatomy

Previous CABG ⁽⁶⁾

- Patients with a previous CABG and all of the following:
 - Patent LIMA to the LAD
 - Clinical indication for revascularization
 - Lesion amenable to PCI

Cardiac Allograft Vasculopathy ⁽⁶⁾

- Cardiac Allograft Vasculopathy
 - Patients with cardiac allograft vasculopathy with severe, proximal, discrete coronary lesions

Revascularization Prior to Percutaneous Valve Procedures

- Patients with significant left main or proximal CAD with/without angina ^(6,7)

Treatment of Calcified Lesions

- Rotational atherectomy ^(6,8,9):
 - Reasonable as primary procedure for fibrotic or heavily calcified de novo lesions for lesion modification prior to angioplasty and stenting:
 - Between >180 - 360 -degree calcification
 - Maximum thickness > 0.5 mm and length > 5 mm
 - Napkin ring calcification

- As secondary approach after unsuccessful attempt to dilate calcified lesion by balloon angioplasty
- Calcification showing reverberation in intravascular ultrasound
- Laser Coronary atherectomy:
 - Reasonable to perform for in stent restenosis ⁽¹⁰⁾

Limitations for Coronary Atherectomy

- Rotational atherectomy is not recommended for below scenarios ⁽⁸⁾ :
 - Occlusions for which a guidewire will not pass (risk of perforation)
 - Degenerated SV Graft lesion or thrombus
 - Lack of cardiac surgery
 - Patient is ineligible for CABG
 - Left ventricular dysfunction
 - Severe multivessel or unprotected left main coronary artery disease lesion length > 25 mm and lesion angulation > 45°
 - Rotational atherectomy should be used cautiously in presence of coronary dissection for plaque modification, provided that guidewire is in true lumen of coronary artery

CODING AND STANDARDS

Codes

92920, 92924, 92928, 92930, 92933, 92937, 92943, 92972, 92973, 92974, C9600, C9601, C9602, C9603, C9604, C9605, C9606, C9607, C9608

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Canadian Cardiovascular Society grading of angina pectoris ⁽¹¹⁾

Grade	Description
Grade I	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation
Grade II	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions
Grade III	Marked limitation of ordinary physical activity. Walking one or two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace
Grade IV	Inability to carry on any physical activity without discomfort, anginal syndrome may be present at rest

Types of Coronary Atherectomy

- Coronary Atherectomy is a procedure that utilizes a catheter device that is inserted into coronary artery percutaneously to remove plaque from the inside of artery.
- In the presence of coronary artery calcification with an arc > 50%, thickness > 0.5 mm and length > 5 mm, adjunctive therapies for calcium modification should be considered, which are:
 - Rotational atherectomy involves the use of a special burr or drill on the tip of a catheter that rotates to shave the plaque into tiny pieces
 - Directional atherectomy, a technique in which a small cutting device is pushed against the plaque to cut it away from the artery. The process can be repeated at the time the treatment is performed to remove a significant amount of disease from the artery, thus eliminating a blockage from atherosclerotic disease. Devices for directional coronary atherectomy are no longer marketed in the United States.
 - Excimer Laser atherectomy involves the use of xenon chloride laser generator to generate laser (pulsating beams of light) to vaporize the calcified plaque in coronary arteries.
 - Orbital atherectomy uses a unique mechanism of action incorporating centrifugal forces via a standard 1.25 mm eccentrically mounted and diamond coated burr to ablate calcified plaque to facilitate stent expansion.

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) is outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

Guideline-directed medical therapy (GDMT) is a part of management of patients with stable ischemic heart disease (SIHD) regardless if revascularization is performed. GDMT for patients with coronary artery disease is synonymous with secondary prevention and consists of pharmacologic therapy with an antiplatelet agent, risk factor modification, and lifestyle interventions. In patients with chronic coronary disease and angina, two antianginals are recommended for relief on angina. ⁽¹²⁾

In patients with refractory angina despite medical therapy and with significant coronary artery stenoses amenable to revascularization, revascularization is recommended to improve symptoms.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

SUMMARY OF EVIDENCE

2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization ⁽⁶⁾

Study Design: This document is a clinical practice guideline developed by the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. It provides recommendations for coronary artery revascularization based on a comprehensive literature review conducted from May 2019 to September 2019, including studies, reviews, and other evidence published in English.

Target Population: The guideline is intended for patients with significant coronary artery disease undergoing coronary revascularization. It aims to guide clinicians in the treatment of these patients, focusing on improving equity of care and shared decision-making.

Key Factors: The guideline covers various aspects of coronary revascularization, including preprocedural assessment, defining lesion severity, revascularization in STEMI and NSTEMI-ACS, special populations and situations, procedural issues for PCI and CABG, pharmacotherapy, psychosocial factors, lifestyle changes, and outcomes.

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease ⁽⁷⁾

Study Design: This document is a clinical practice guideline developed by the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. It provides recommendations for the management of patients with valvular heart disease based on an extensive literature review conducted through March 1, 2020.

Target Population: The guideline is intended for adult patients with valvular heart disease, including those with aortic stenosis, aortic regurgitation, bicuspid aortic valve, mitral stenosis, mitral regurgitation, tricuspid valve disease, pulmonic valve disease, mixed valve disease, prosthetic valves, infective endocarditis, and valvular heart disease during pregnancy.

Key Factors: The guideline covers the evaluation of patients with known or suspected valvular heart disease, definitions of severity, diagnosis and follow-up, medical therapy, surgical and interventional risk, the multidisciplinary heart valve team, management after valve intervention, and specific recommendations for different types of valvular heart disease.

North American Expert Review of Rotational Atherectomy ⁽⁸⁾

Study Design: This document is a consensus review by experienced North American rotational atherectomy operators and device experts. It summarizes and critiques key elements of contemporary rotational atherectomy technique, identifies areas of consensus and controversy, and offers recommendations for optimal performance.

Target Population: The review focuses on patients undergoing percutaneous coronary intervention for calcified coronary lesions, particularly those with severe coronary artery calcification.

Key Factors: The review covers the rationale for rotational atherectomy, patient and lesion selection, contraindications and cautions, special situations (such as ostial and bifurcation lesions, left main disease, chronic total occlusion, and aortic stenosis with plan for transcatheter aortic valve replacement), device selection, technical performance, recognition and management of complications, and expectations for operators and institutions.

ANALYSIS OF EVIDENCE

Shared Findings ^(6–8)

- All three articles emphasize the importance of a multidisciplinary approach to PCI, involving specialized teams and centers to optimize patient outcomes.
- They highlight the need for careful patient and lesion selection, preprocedural assessment, and shared decision-making to ensure the best possible outcomes.
- The articles support the use of PCI in various clinical scenarios, including coronary artery disease, valvular heart disease, and calcified coronary lesions.

Conclusion

In summary, while all three documents provide valuable insights into different aspects of cardiovascular disease management, they each focus on distinct areas: coronary artery revascularization, valvular heart disease, and rotational atherectomy. The shared emphasis on multidisciplinary team approaches and individualized treatment plans highlights the importance of comprehensive and patient-centered care in cardiovascular medicine.

POLICY HISTORY

Date	Summary
December 2025	<ul style="list-style-type: none"> Added the following CPT Codes for Evolent prior authorization scope: 92972, 92974, C9600, C9601, C9602, C9603, C9604, C9605, C9606, C9607, C9608 Codes within the coding section were edited to reflect changes made by the American Medical Association. Deleted: 92921, 92925, 92929, 92934, 92938, 92944. Added: 92930
June 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> This guideline replaces Evolent Clinical Guideline 7318 for Percutaneous Coronary Interventions This guideline replaces Evolent Clinical Guideline 7273 for Coronary Atherectomy

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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Evolent Clinical Guideline 7315 for Pacemaker Insertion

Guideline Number: Evolent_CG_7315	<u>Applicable Codes</u>	
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Original Date: January 2026	Last Revised Date: July 2025	Implementation Date: January 2026

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

This guideline is not intended to specify the type of bradycardia pacing device. CRT (cardiac resynchronization therapy or biventricular pacing) and ICD (implantable cardioverter defibrillator) implantation are covered in separate guidelines. Pacemaker implantation generally serves to address bradycardia, with the intention of ameliorating related symptoms, preventing complications of syncope, and/or reducing mortality risk.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1–5)

INDICATIONS FOR PACEMAKERS IN ADULTS

Excludes conditions that are expected to resolve.

Sinus Node Dysfunction (SND) (6–9)

- Documented symptomatic sinus bradycardia, including frequent sinus pauses
- Symptomatic chronotropic incompetence (broadly defined as an inability to increase heart rate commensurate with activity or demand), documented by stress test or cardiac monitoring data
- Symptomatic sinus bradycardia resulting from required guideline-directed medical therapy (GDMT) for which there is no alternative treatment
- Heart rate < 40 beats per minute (bpm) while awake, even without definite association with significant symptoms consistent with bradycardia
- Tachycardia-bradycardia syndrome and symptoms attributable to bradycardia
- Syncope of unexplained origin with clinically significant SND, either documented or provoked in electrophysiologic study (EPS)
- With LBBB and LVEF < 50% (**AUC 6**)

Acquired Atrioventricular (AV) Block (6,7,9)

First-Degree AV Block

- Marked first-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block
- First-degree block with a long PR interval (>200 ms) and LVEF ≤ 35% (**AUC 7**) or 36–50% (**AUC 6**)
- First-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise

Second Degree AV Block (Mobitz Types I and II)

- Second degree Mobitz Type 1 AV Block with a narrow QRS and LVEF ≤ 35% (**AUC 7**) or 36–50% (**AUC 6**)
- Marked second-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block
- Second-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise
- Second-degree Mobitz Type II AV block regardless of symptoms¹
- Advanced second-degree AV block
- Second-degree AV block with EPS-documented intra- or infra-His conduction delay of 70 ms or greater
- Symptomatic bradycardia associated with second-degree AV block, either Mobitz I or II

Third-Degree/Complete AV Block

- Third-degree (complete) AV block, intermittent with LVEF \leq 35% (**AUC 7**) or 36-50% (**AUC 6**) or persistent, regardless of symptoms and LVEF $<$ 50% (**AUC 7**) or $>$ 50% (**AUC 6**)
 - If the only symptom is a narrow junctional escape rhythm and LVEF is $>$ 50%, pacemaker is not indicated (**AUC 5**)
- High-grade AV block, regardless of symptoms

Atrial Fibrillation (AF)/Other^(6,7,9)

- AF, with pauses \geq 5 seconds while awake, or symptomatic bradycardia
- In sinus rhythm (with AV block) while awake, pauses \geq 3 seconds or heart rate $<$ 40 bpm or an escape rhythm below the AV node
- Following catheter ablation of the AV junction
- Symptomatic AV block that results from required medical therapy for which there is no alternative treatment
- Exercise-induced second- or third-degree AV block without myocardial ischemia
- With slow ventricular response and LVEF $<$ 50% (**AUC 7**)

Neuromuscular Disorders^(6,7)

- Marked first-degree or higher AV block, or an H-V (His-ventricular) interval \geq 70 ms, associated with neuromuscular diseases, such as myotonic muscular dystrophy, Erb's dystrophy, Kearns-Sayre syndrome, and peroneal muscular atrophy, regardless of symptoms

Chronic Fascicular Block*^(6,7,10)

*includes right bundle branch (RBBB), left bundle branch (LBBB), left anterior hemi (LAHB), and left posterior hemi (LPHB) block

- Alternating bundle-branch block
- Syncope and bundle branch block with an H-V interval \geq 70 ms, or evidence of infranodal block at EPS
- Incidental findings at EPS study of an H-V interval \geq 100 milliseconds, or non-physiological, pacing-induced infra-His block in asymptomatic patients Hypersensitive Carotid Sinus Syndrome And Neurocardiogenic Syncope
- Recurrent syncope due to spontaneously occurring carotid sinus stimulation AND carotid sinus pressure induced ventricular asystole \geq 3 seconds⁽⁶⁾, or AV block, or \geq 50 mmHg drop in systolic blood pressure (BP)
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole) \geq 3 seconds

- Recurrent syncope and asystole ≥ 3 seconds with syncope or ≥ 6 seconds without symptoms or with presyncope, documented by ECG recording data

Pacing to Terminate or Prevent Tachycardia ⁽⁶⁾

- Symptomatic recurrent supraventricular tachycardia documented to be terminated by pacing in the setting of failed catheter ablation and/or drug treatment
- Prevention of pause-dependent VT

Hypertrophic Cardiomyopathy (HCM) ⁽⁶⁾

- Permanent pacing may be considered in medically refractory symptomatic patients with HCM and significant resting or provoked left ventricle (LV) outflow tract obstruction

Leadless Pacemakers ⁽⁹⁾

Leadless pacemakers can only provide ventricular pacing but have fewer complications than transvenous pacemakers. Therefore, permanent pacing via leadless pacemaker is indicated for patients with nonreversible symptomatic bradycardia who are not eligible for an implantable cardioverter defibrillator (ICD), and have one or more of the following:

- No upper extremity access and left ventricular ejection fraction (LVEF) $> 50\%$ (**AUC 7**)
- Long-standing persistent or permanent AF and normal LVEF, when the longevity of the device is anticipated to be greater than patient survival, and the need for pacing is anticipated as $< 40\%$ (**AUC 7**)
- History of multiple cardiovascular implantable electronic device (CIED) infections, LVEF $> 50\%$ and need for pacing anticipated as $< 40\%$ (**AUC 7**)
- AV junction ablation and long-standing persistent/permanent AF, LVEF $> 50\%$ (**AUC 7**)
- Pre-existing subcutaneous ICD and need for pacing anticipated as $< 40\%$
 - LVEF $> 50\%$ and persistent/permanent AF (**AUC 7**) OR
 - Paroxysmal AF (**AUC 7**)

INDICATIONS FOR CHILDREN, ADOLESCENTS (<19 YEARS), AND ADULT PATIENTS WITH CONGENITAL HEART DISEASE (CHD)

Sinus Node Dysfunction ^(7,11)

- SND with symptomatic age- and activity-inappropriate bradycardia
- Sinus bradycardia with complex CHD AND a resting heart rate < 40 bpm **OR** pauses in ventricular rate > 3 seconds

- CHD and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony
- Asymptomatic sinus bradycardia following repair of CHD with an awake resting heart rate < 40 bpm or pauses in ventricular rate > 3 seconds
- CHD and SND or junctional bradycardia, for the prevention of recurrent episodes of intra-atrial reentrant tachycardia

AV Block (6–8)

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output
- Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction
- Postoperative advanced second- or third-degree AV block that is not expected to resolve or that persists at least 7 days after cardiac surgery
- Congenital third-degree AV block in the infant with a ventricular rate < 55 bpm or with congenital heart disease and a ventricular rate < 70 bpm
- Congenital third-degree AV block after 1 year of age with an average heart rate < 50 bpm, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptoms due to chronotropic incompetence
- Adults with congenital complete AV block with symptomatic bradycardia, wide QRS escape rhythm, mean daytime heart rate < 50 bpm, complex ventricular ectopy, or ventricular dysfunction
- Adults with congenital complete AV block, regardless of symptoms
- Unexplained syncope after prior congenital heart surgery complicated by transient complete heart block, with residual fascicular block after excluding other causes of syncope
- Congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS, and normal ventricular function

CODING AND STANDARDS

Codes

33206, 33207, 33208, 33212, 33213, 33215, 33216, 33217, 33218, 33220, 33274, 33275

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial

<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- *Appropriate Care - Median Score 7-9*
- *May be Appropriate Care - Median Score 4-6*
- *Rarely Appropriate Care - Median Score 1-3*

Heart Block Definitions ⁽⁶⁾

- First-Degree: All sinus or atrial beats are conducted to the ventricles, but with a delay (PR interval of > 200 ms)
- Second-Degree: Intermittent failure of conduction of single beats from atrium to ventricles
 - (Mobitz) Type I: Conducted beats have variable conduction times from atrium to ventricles
 - (Mobitz) Type II: Conducted beats have uniform conduction times from atrium to ventricles
 - Advanced or high degree: Two or more consecutive non-conducted sinus or (non-premature) atrial beats with some conducted beats
- Third-Degree: No atrial beats are conducted from atrium to ventricle

Acronyms / Abbreviations

AV: Atrioventricular

BP: blood pressure

BPM: beats per minute

CHF: Congestive heart failure

CRT: Cardiac resynchronization therapy (same as biventricular pacing)

ECG: Electrocardiogram

EPS: Electrophysiologic Study
GDMT: Guideline-Directed Medical Therapy
HCM: Hypertrophic cardiomyopathy
H-V: His-ventricular
ICD: Implantable cardioverter-defibrillator
LAHB: Left Anterior Hemiblock
LBBB: Left bundle-branch block
LPHB: Left Posterior Hemiblock
LV: Left ventricular/left ventricle
LVEF: Left ventricular ejection fraction
MI: Myocardial infarction
ms: Milliseconds
RBBB: Right Bundle Branch Block
s: Seconds
STEMI: ST-elevation Myocardial Infarction
SND: Sinus node dysfunction
VT: Ventricular tachycardia

SUMMARY OF EVIDENCE

2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities⁽⁶⁾

Study Design: This document is a guideline developed by the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines, in collaboration with several other medical societies. It includes recommendations based on a comprehensive literature search and evidence review.

Target Population: The guidelines focus on patients with hypertrophic cardiomyopathy, including adults, children, and adolescents. It addresses the diagnosis, risk assessment, and management of HCM, including the use of ICDs for SCD prevention.

Key Factors

- **Risk Assessment:** The document highlights the importance of SCD risk assessment in HCM patients, including factors such as family history of SCD, maximal LV wall thickness, unexplained syncope, LV apical aneurysm, extensive LGE, and NSVT episodes.
- **ICD Placement:** Recommendations for ICD placement in high-risk HCM patients consider individual clinical judgment, shared decision-making, and the presence of major risk factors.

- **Device Selection:** The guidelines discuss the selection of ICD devices, including single-chamber, dual-chamber, and subcutaneous ICDs, based on patient preferences and clinical needs.
- **Management:** The document provides recommendations for the pharmacological and invasive treatment of symptomatic HCM patients, including the use of beta blockers, calcium channel blockers, myosin inhibitors, and septal reduction therapies.

2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay⁽⁷⁾

Study Design: This document is a guideline developed by the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society, in collaboration with several other medical societies. It includes recommendations based on a comprehensive literature search and evidence review.

Target Population: The guidelines focus on patients with bradycardia and cardiac conduction delay, including adults with sinus node dysfunction (SND), atrioventricular (AV) block, and other conduction disorders. It addresses the diagnosis, risk assessment, and management of these conditions.

Key Factors

- **Risk Assessment:** The document emphasizes the importance of identifying reversible causes of bradycardia and conduction delay, such as medications, electrolyte imbalances, and underlying medical conditions.
- **Device Selection:** Recommendations for pacemaker implantation consider patient preferences, age, lifestyle, and clinical needs.
- **Management:** The guidelines provide recommendations for the acute and chronic management of bradycardia and conduction delay, including the use of temporary and permanent pacing.

ACC/AHA/ASE/HFSA/HRS/SCAI/SCCT/SCMR 2025 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy, and Pacing⁽⁹⁾

Study Design: The study involved the development of Appropriate Use Criteria (AUC) for ICDs, cardiac resynchronization therapy (CRT), and pacing. The process included drafting clinical scenarios based on patient presentations encountered in everyday practice. These scenarios were evaluated by an independent rating panel using a scoring scale from 1 to 9.

Target Population: The study focused on patients who may require ICDs, CRT, or pacing therapies. This includes patients with coronary artery disease (CAD), nonischemic cardiomyopathy (CM), genetic arrhythmia diseases, heart failure (HF), and those with left ventricular assist devices (LVADs).

Key Factors:

- **Clinical Scenarios:** The scenarios included information on symptom status, risk level as assessed by noninvasive testing, coronary disease burden, and in some cases, fractional flow reserve testing, presence or absence of diabetes, and SYNTAX score.
- **Scoring:** Each indication was scored as “Appropriate” (7 to 9), “May Be Appropriate” (4

to 6), or “Rarely Appropriate” (1 to 3).

- **Therapy Options:** The study evaluated the appropriateness of ICDs, CRT, and pacing therapies for various clinical scenarios.
- **Emphasis:** The study emphasized the importance of guideline-directed medical therapy and antianginal therapy in the management of patients.
- **Patient Preference:** The study highlighted the role of shared decision-making and patient preferences in the selection of therapy options.

ANALYSIS OF EVIDENCE

Shared Conclusions

All three articles emphasize the importance of evidence-based practice and provide detailed guidelines for pacemaker implantation based on clinical evidence. They all address specific conditions requiring pacing and offer recommendations for the evaluation and management of patients with bradycardia and conduction disorders. Additionally, they highlight the importance of correlating symptoms with bradycardia and conduction disorders to ensure appropriate management.

In summary, these articles collectively provide a comprehensive understanding of pacemaker implantation, highlighting the importance of evidence-based practice, detailed evaluation, and management of bradycardia and conduction disorders, while also addressing specific conditions and emphasizing patient-centered care.

POLICY HISTORY

Date	Summary
July 2025	<ul style="list-style-type: none"> ● Reviewed to reconcile dates, no substantive changes made
June 2025	<ul style="list-style-type: none"> ● Added third bullet to General Information ● Added Summary of Evidence and Analysis of Evidence ● This guideline merges two Evolent guidelines with identical clinical criteria: ECG 7315-01 for Pacemaker Implantation and ECG 322 for Pacemaker <ul style="list-style-type: none"> ○ This guideline also merges procedural codes ● Guideline name changed to Pacemaker Insertion
April 2025	<ul style="list-style-type: none"> ● Guideline number changed to 7315 ● Updated citations

Date	Summary
	<ul style="list-style-type: none"> • Updated indications for leadless pacemakers • Updated indications for chronic fascicular block • Removed Contraindications • Reduced Background

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

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Evolent Clinical Guideline 7334 for Transcatheter Aortic Valve Replacement (TAVR)

Guideline Number: Evolent_CG_7334	<u>Applicable Codes</u>	
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Original Date: May 2016	Last Revised Date: December 2025	Implementation Date: January 2026

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STATEMENT

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- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for Transcatheter Aortic Valve Replacement (TAVR).

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

INDICATIONS FOR TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

Symptomatic

- Symptoms or signs with activities of daily living or with physiologic testing (i.e., exercise treadmill test) include exertional dyspnea, decreased exercise tolerance, exertional angina, heart failure, exertional syncope, pre-syncope, or abnormal blood pressure response on exercise treadmill test (see **Definitions**) ^(6,7)

- Severe (see **Definitions**) aortic stenosis (AS) in patients of any age ⁽⁶⁾:
 - High or prohibitive surgical risk as determined by the Society of Thoracic Surgeons predicted risk of mortality score (STS-PROM, see **Definitions**) for conventional surgical AVR (SAVR) **AND**
 - Predicted post-TAVR survival > 12 months **AND**
 - Acceptable quality of life (> 1 year)
 - Severe AS, > 80 years of age or for younger patients with life expectancy < 10 years ⁽⁶⁾
 - Severe AS, 65 to 80 years of age, as an alternative to SAVR after shared decision-making related to valve durability and expected longevity ⁽⁶⁾
- Note:** Surgical aortic valve replacement (SAVR) recommended if patient is < 65 years of age or has life expectancy > 20 years ⁽⁶⁾
- Severe AS with multiple comorbidities (high or extreme risk patients) ⁽⁷⁾:
 - Frail (see **Definitions**) with fatigue but no chest pain or shortness of breath
 - Severe AS, high surgical risk
 - B-type Natriuretic Peptide (BNP) elevated (**AUC Score 7**)
 - Normal BNP (**AUC Score 5**)
 - Very severe AS (see **Definitions**), high surgical risk
 - Normal BNP (**AUC Score 7**)
 - BNP elevated (**AUC Score 8**)
 - Oxygen dependent pulmonary disease with dyspnea
 - High surgical risk
 - BNP normal (**AUC Score 7**)
 - BNP elevated (**AUC Score 8**)
 - End-stage renal disease on dialysis with symptomatic AS
 - Extreme surgical risk, multiple comorbidities, not a renal transplant candidate, longstanding dialysis (**AUC Score 6**)
 - High surgical risk, nondiabetic/nonthypertensive etiology, renal transplant candidate, short time on dialysis (**AUC Score 7**)
 - Cirrhosis (high surgical risk) (**AUC Score 7**)
 - Malignancy with high surgical risk
 - Life expectancy > 1 year (**AUC Score 7**)
 - Severe AS with additional anatomical risks not captured in the STS-PROM such as hostile chest or porcelain aorta (see **Definitions**); and otherwise, low, intermediate or high surgical risk by STS-PROM score (**AUC Score 8**) ⁽⁷⁾
 - Prior to non-cardiac surgery with nonobstructive coronary artery disease (CAD), as an alternative to SAVR ⁽⁷⁾:

- Severe/very severe AS, elective major surgery planned **(AUC Score 8)**
- Severe/very severe AS, urgent major surgery planned **(AUC Score 7)**
- Severe AS with associated CAD (i.e., TAVR plus percutaneous coronary intervention (PCI) as an alternative to SAVR plus CABG) ⁽⁷⁾
 - 1 or 2 vessel CAD, with or without proximal left anterior descending artery (LAD) involvement:
 - High or intermediate surgical risk **(AUC Score 7)**
 - 3-vessel CAD:
 - Low (< 22) SYNTAX score (see **Definition**):
 - High or intermediate surgical risk **(AUC Score 7)**
 - Intermediate or high (≥ 22) SYNTAX score:
 - High or intermediate surgical risk **(AUC Score 6)**
 - Left main coronary artery:
 - Intermediate or low (< 33) SYNTAX score:
 - High or intermediate surgical risk **(AUC Score 7)**
 - High (≥ 33) SYNTAX score:
 - High or intermediate surgical risk **(AUC Score 6)**
- Severe AS with other valve or anatomical pathology ⁽⁷⁾:
 - Severe rheumatic mitral stenosis (MS) and no contraindication to balloon mitral valvuloplasty (i.e., TAVR plus balloon mitral valvuloplasty):
 - High surgical risk **(AUC Score 7)**
 - Severe primary (see **Definitions**) mitral regurgitation (i.e., TAVR plus mitral transcatheter edge-to-edge repair (TEER))
 - High surgical risk **(AUC Score 6)**
 - Severe secondary (see **Definitions**) tricuspid regurgitation with dilated right ventricle and/or tricuspid valve annulus ≥ 40mm, moderate to severe right ventricular dysfunction and:
 - Moderate to severe pulmonary hypertension, high surgical risk **(AUC Score 7)**
 - Minimal pulmonary hypertension, intermediate surgical risk **(AUC Score 5)**
 - Prominent basal left ventricular hypertrophy with left ventricular outflow tract (LVOT) obstruction (narrowing with flow acceleration) and intermediate or high surgical risk **(AUC Score 6)**
- Failing aortic valve bioprosthesis (i.e., valve-in-valve procedure for severe AS or aortic regurgitation (AR) and degenerative surgical bioprosthesis) ⁽⁷⁾
 - Bioprosthesis size ≥ 23 mm:
 - High surgical risk **(AUC Score 8)**

- Intermediate surgical risk (**AUC Score 7**)
- Bioprosthesis size 21 mm:
 - High surgical risk (**AUC Score 6**)
 - Intermediate surgical risk (**AUC Score 5**)
- Bioprosthesis size ≤ 19 mm:
 - High surgical risk (**AUC Score 5**)
- AVA (aortic valve area) ≤ 1.0 cm² (or AVA index ≤ 0.6 cm²/m²) on resting echo, low flow/low gradient (see **Definitions**), with severely calcified valve, and clinical, hemodynamic and anatomic data support valve obstruction as the most likely cause of symptoms, as an alternative to SAVR ⁽⁷⁾:
 - High or intermediate surgical risk (**AUC Score 8**)
 - Low surgical risk (**AUC Score 9**)

Asymptomatic

- Severe AS and LVEF $< 50\%$, and ≤ 80 years of age as an alternative to SAVR after shared decision-making related to valve durability and expected longevity, including the following situations ^(6,7):
 - AVA (aortic valve area) ≤ 1.0 cm² (or AVA index ≤ 0.6 cm²/m²) on resting echo, **LVEF $< 20\%$** , high or intermediate risk for surgery:
 - Aortic valve peak velocity ≥ 4 m/s or mean gradient ≥ 40 mmHg on resting echo (**AUC Score 7**)
 - AVA (aortic valve area) ≤ 1.0 cm² (or AVA index ≤ 0.6 cm²/m²) on resting echo, **LVEF $< 20\%$** , low flow/low gradient with flow reserve on dobutamine echocardiogram (i.e., truly severe AS):
 - High or intermediate surgical risk (**AUC Score 7**)
 - AVA (aortic valve area) ≤ 1.0 cm² (or AVA index ≤ 0.6 cm²/m²) on resting echo, **LVEF 20%-49%**, low flow/low gradient with flow reserve on dobutamine echocardiogram (i.e., truly severe AS):
 - High or intermediate surgical risk (**AUC Score 8**)
 - Low surgical risk (**AUC Score 9**)
 - AVA (aortic valve area) ≤ 1.0 cm² (or AVA index ≤ 0.6 cm²/m²) on resting echo, **LVEF 20%-49%**, low flow/low gradient with no flow reserve on dobutamine echocardiogram but with very calcified valve on imaging (TTE or CT) or projected valve area calculation suggesting truly severe AS:
 - High or intermediate surgical risk (**AUC Score 7**)
- Severe AS and LVEF $\geq 50\%$ with low surgical risk (see **Definitions**), with a high-risk profession (e.g., airline pilot), lifestyle (competitive athlete), or anticipated prolonged period away from medical supervision ⁽⁷⁾ (**AUC Score 7**)

- Very severe AS, LVEF $\geq 50\%$ ⁽⁷⁾:
 - High or intermediate surgical risk (**AUC Score 7**)
 - Low surgical risk (**AUC Score 8**)
- Severe AS prior to non-cardiac surgery with nonobstructive CAD, as an alternative to SAVR ⁽⁷⁾:
 - Severe/very severe AS, elective major surgery planned (**AUC Score 7**)
 - Severe/very severe AS, urgent major surgery planned (**AUC Score 5**)
- Severe AS, LVEF $\geq 50\%$, with ≥ 1 predictor(s) of symptom onset or of rapid progression such as: rapid progression (peak velocity increasing > 0.3 m/s per year, severe valve calcification, elevated BNP, significant LVH in the absence of hypertension), and a negative ETT, as an alternative to SAVR ⁽⁷⁾:
 - High or intermediate surgical risk (**AUC Score 7**)
 - Low surgical risk (**AUC Score 8**)

CODING AND STANDARDS

Codes

33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368

Places of Service

Inpatient hospital (21)

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- Aortic Stenosis Severity ⁽⁶⁾:
 - Severe AS: Aortic peak velocity (Vmax) ≥ 4 m/s or mean gradient ≥ 40 mm Hg
 - Aortic valve area (AVA) typically is ≤ 1.0 cm² (or valve index (AVAi) 0.6 cm²/m²) but is not required to define severe AS ⁽⁶⁾
 - Very severe AS: aortic Vmax ≥ 5 m/s or mean gradient ≥ 60 mm Hg
 - Low flow/low gradient severe AS: defined by a mismatch between reduced aortic valve area (AVA, < 1 cm²) and a non-severe increase mean valve pressure gradient (i.e., < 40 mmHg) with an impaired left ventricular stroke volume (volume of blood pumped with each beat, similar to LVEF) at rest. This creates a diagnostic and therapeutic dilemma: choosing between aortic valve replacement (AVR) and medical therapy vs optimal medical therapy alone. Low dose dobutamine stress echo (DSE) is recommended as a means of increasing stroke volume with a simultaneous reassessment of aortic valve indices. **Flow reserve** is defined as a 20% increase in stroke volume demonstrated by DSE. DSE can yield three possible results in this situation:
 - Truly severe AS: Significant increase in stroke volume (i.e. flow reserve is demonstrated) and mean valve gradient (>40 mmHg). Aortic valve is severely stenotic, and the low gradient measured at rest is a consequence of the LV contractile dysfunction.
 - Pseudo-severe AS: Significant increase in stroke volume and persistent low mean valve gradient (< 40 mmHg) and AS does not meet the hemodynamic criteria to be defined as severe.
 - Undetermined AS severity: Absence of significant increase in stroke volume and mean valve gradient (< 40 mmHg): In this case, DSE fails to demonstrate an increase in stroke volume (lack of flow reserve) and the AS severity grade remains undetermined. In this situation clinicians have to rely on the morphologic features of the valve on imaging (such as cardiac CT). ⁽⁸⁾
- Risk Assessment for Valve Procedures:
 - **STS-PROM** (Society of Thoracic Surgeons predicted risk of surgical mortality) ^(6,7)
 - Low risk: STS score $< 3\%$
 - Intermediate: STS score 3 to 8%
 - High: STS score $> 8\%$ to $<15\%$
 - Extreme: STS score $\geq 15\%$
 - Society of Thoracic Surgeons (STS) Risk Calculations
 - The Society of Thoracic Surgeons Risk Calculator is an interactive algorithm that produces risk percentages for a range of likelihoods based on specific patient characteristics. It draws from a database that incorporates data on all adult

cardiac surgical procedures. The calculator can be located at the Society of Thoracic Surgeons website, www.sts.org.

- Anatomical Factors Favoring TAVR over Surgical Valve Replacement

Note: these anatomical factors increase surgical risk and are not captured in the STS-PROM risk calculator ⁽⁷⁾

- Porcelain aorta: severe calcification of the ascending aorta extending to the aortic arch preventing safe cannulation or cross-clamping during cardiac surgery ⁽⁹⁾
- Hostile chest: condition(s) that make chest surgery prohibitively risky such as radiation damage, abnormal chest wall anatomy (i.e. severe kyphoscoliosis), complications from prior surgery ⁽¹⁰⁾

- **SYNTAX** Score - SYNTAX (Synergy between PCI with Taxus and Cardiac Surgery) Score ⁽¹¹⁾

Note: The SYNTAX score is designed to predict outcomes of coronary revascularization by grading the complexity of coronary artery lesions. A higher score indicates more complex coronary artery disease and would favor surgical revascularization (CABG) over PCI.

- Low (0-22)
- Intermediate (23-32)
- High >33

- Frailty ⁽⁷⁾

- Determining whether a patient is symptomatic from AS can be difficult, particularly in elderly, sedentary population that often has multiple comorbidities. Frailty falls along a spectrum and is characterized as impaired resilience to stressors. This information is considered when assessing patient reported symptoms, procedural risk, and anticipated benefit after the various treatment options. ⁽⁷⁾ There is no universal definition of frailty, and many criteria have been proposed. The Fried criteria ⁽¹²⁾ are commonly used:

- Slow gait speed
- Weak handgrip
- Exhaustion
- Physical inactivity
- Weight loss

- Abnormal ETT Definition ⁽⁷⁾

- In relation to the functional assessment of seemingly asymptomatic AS, an abnormal exercise stress test is characterized by:
 - Exercise-induced angina
 - Excessive dyspnea early in exercise
 - Dizziness, or syncope

- Limited exercise capacity (below age and sex-specific predicted metabolic equivalent of task, or MET)
- Abnormal blood pressure response (e.g., hypotension during exercise or failure to increase blood pressure with exercise)
- Increase in the mean gradient with exercise ≥ 18 mmHg (i.e., on stress echocardiogram)

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AR: Aortic regurgitation

AS: Aortic stenosis

AVA: Aortic valve area

BNP: B-type natriuretic peptide

CABG: Coronary artery bypass grafting

CAD: Coronary artery disease

CT: Computed tomography

ETT: Exercise treadmill test

LAD: Left anterior descending artery

LVEF: Left ventricular ejection fraction

LVH: Left ventricular hypertrophy

LVOT: Left ventricular outflow tract

MS: Mitral stenosis

PCI: Percutaneous coronary intervention

SAVR: Surgical aortic valve replacement

STS-PROM: Society of Thoracic Surgeons predicted risk of mortality score

SYNTAX: Synergy between PCI with Taxus and Cardiac Surgery

TAVR: Transcatheter aortic valve replacement

TEER: Transcatheter edge-to-edge repair

TTE: Transthoracic echocardiogram

SUMMARY OF EVIDENCE

ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for the Treatment of Patients With Severe Aortic Stenosis ⁽⁷⁾

Study Design

The study focuses on the appropriate use criteria (AUC) for the treatment of patients with severe aortic stenosis (AS). It is a comprehensive report developed by the American College of Cardiology (ACC) Appropriate Use Criteria Task Force in collaboration with several other cardiovascular societies. The study involves the identification of common patient scenarios, assumptions, definitions, and treatment options for severe AS, including surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR). The study uses a modified Delphi process for rating the clinical scenarios and combines evidence-based medicine with practice experience.

Target Population

The target population includes patients with severe aortic stenosis, categorized into various stages based on symptoms, valve anatomy, valve hemodynamics, and changes in the left ventricle (LV) and vasculature. The study specifically addresses patients with high-gradient severe AS, low-flow low-gradient severe AS with reduced or normal LV ejection fraction (LVEF), and asymptomatic severe AS.

Key Factors

- **Severity of AS:** The study defines severe AS based on maximum aortic velocity, mean pressure gradient, and valve area. It also considers low-flow low-gradient AS and the degree of aortic valve calcification.
- **Treatment Options:** The study evaluates the appropriateness of SAVR, TAVR, balloon aortic valvuloplasty (BAV), and conservative management with no intervention. It provides detailed criteria for each treatment option based on clinical scenarios.
- **Clinical Outcomes:** The study discusses the impact of various treatment options on survival, symptoms, and LV systolic function. It emphasizes the importance of timely intervention to prevent irreversible consequences of severe AS.
- **Multidisciplinary Approach:** The study highlights the role of a multidisciplinary heart valve team in the evaluation and management of patients with severe AS

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease ⁽⁶⁾

Study Design

The study presents the 2020 ACC/AHA Guideline for the management of patients with valvular heart disease (VHD). It is a clinical practice guideline developed by the American College of Cardiology (ACC) and the American Heart Association (AHA) Joint Committee on Clinical Practice Guidelines. The study involves a systematic review of literature, evidence-based recommendations, and a modular format for presenting the guidelines.

Target Population

The target population includes adult patients with various types of valvular heart disease, including aortic stenosis, aortic regurgitation, bicuspid aortic valve, mitral stenosis, mitral regurgitation, tricuspid valve disease, and prosthetic valves.

Key Factors

- **Disease Stages:** The study classifies valvular heart disease into stages (A, B, C, and D) based on symptoms, valve anatomy, severity of valve dysfunction, and the response of the ventricle and pulmonary circulation.
- **Diagnostic Testing:** The study provides recommendations for diagnostic testing, including echocardiography, cardiac catheterization, exercise testing, and imaging modalities such as CT and CMR.
- **Medical Therapy:** The study discusses the role of medical therapy in managing valvular heart disease, including hypertension treatment, anticoagulation for atrial fibrillation, and secondary prevention of rheumatic fever.
- **Interventional and Surgical Risk:** The study emphasizes the importance of evaluating surgical and interventional risk using online tools and shared decision-making processes.
- **Multidisciplinary Heart Valve Team:** The study highlights the role of a multidisciplinary heart valve team and heart valve centers in optimizing patient outcomes

ANALYSIS OF EVIDENCE

Shared Findings ^(6,7):

- **Appropriateness of TAVR:** Both documents agree that TAVR is an appropriate treatment option for patients with severe symptomatic AS, particularly for those at intermediate or high surgical risk.
- **Guideline References:** Both documents reference the AHA/ACC guidelines for the management of patients with valvular heart disease as primary sources for their recommendations.
- **Patient Selection:** Both documents emphasize the importance of patient selection for TAVR, considering factors such as symptoms, LV function, and surgical risk

Conclusion ^(6,7)

In summary, both documents provide valuable insights into the use of TAVR for treating severe AS, with shared conclusions on its appropriateness and patient selection. However, they differ in their approach to rating the appropriateness of TAVR, the classification of disease stages, and the emphasis on diagnostic testing.

POLICY HISTORY

Date	Summary
December 2025	<ul style="list-style-type: none"> Added the following CPT Codes for Evolent prior authorization scope: 33367, 33368
June 2025	<ul style="list-style-type: none"> Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices No clinical changes Removed code description Adjusted applicable lines of business – Medicare Advantage checked
December 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1295 Transcatheter Aortic Valve Replacement (TAVR) Updated clinical indications for Transcatheter Aortic Valve Replacement Updated Background section Removed Special Note and Limitation sections Updated references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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