



# **2025 Evolent Clinical Guidelines for Medical Necessity Review**

EXPANDED CARDIAC GUIDELINES

Effective January 1, 2025 – December 31, 2025

# 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 062-1 FOR FRACTIONAL FLOW RESERVE CT

<b>Guideline or Policy Number:</b> Evolut_CG_062-1	<b><u>Applicable Codes</u></b>	
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<b>Original Date:</b> August 2017	<b>Last Revised Date:</b> February 2024	<b>Implementation Date:</b> January 2025

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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.*

### Purpose

Fractional flow reserve computed tomography (FFR<sub>CT</sub>) is a technology that estimates the effect of coronary arterial narrowing on blood flow based upon the images acquired in the CCTA study. Its role is to provide information that can more appropriately select patients requiring invasive coronary angiography. <sup>(1)</sup>

## 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.

In instances where an AUC has not been established through prior publication, 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. <sup>(2,3,4,5,6)</sup>

## INDICATIONS FOR FRACTIONAL FLOW RESERVE CT

- Intermediate degrees of stenosis (40 - 90%) on coronary computerized tomographic angiography (CCTA) to guide decision making and help identify those patients who would benefit from revascularization <sup>(1,7,8,9)</sup> (**AUC 8**) <sup>(10)</sup>
- Intermediate lesions in the above range and coronary calcification have made percentage stenosis interpretation difficult, thus could support approval of FFR<sub>CT</sub>, in conjunction with the above criteria. <sup>(11,12)</sup>



## Additional Information

The following clinical scenarios below do not apply for the use of FFR<sub>CT</sub>: <sup>(11)</sup>

- Problematic artifacts, and/or clinical circumstances:
  - When patients have artifacts (heavy calcium) or body habitus (BMI > 35) that could interfere with the examination, the suitability for FFR<sub>CT</sub> is at the discretion of the vendor who provides the FFR<sub>CT</sub> service
  - Known ischemic coronary artery disease that has not been revascularized and there has been no change in patient status or in the CCTA images
- Recent myocardial infarction within 30 days <sup>(13)</sup>
- Prior coronary artery bypass graft surgery
- Complex congenital heart disease or ventricular septal defect (VSD) with pulmonary-to-systemic flow ratio > 1.4
- Metallic stents ≤ 3.0 mm in diameter in the coronary system
- Coronary lesions with a vessel diameter < 1.8 mm <sup>(14,15)</sup>
- Severe wall motion abnormality on CCTA results
- Severe myocardial hypertrophy
- High risk indicators on stress test <sup>(15)</sup>
- Coronary angiography within the past 90 days <sup>(15)</sup>
- Marginal quality of the submitted imaging data, due to motion, blooming, misalignment, arrhythmia, etc.

## CODING AND STANDARDS

### Coding

#### CPT Codes

75580

#### 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

### ***General Overview***

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 <sup>(16)</sup>. During coronary catheterization, a catheter is inserted into the femoral (groin) or radial arteries (wrist) using a sheath and guidewire. FFR uses a small sensor (transducer) on the tip of the wire to measure pressure, temperature, and flow in order to determine the exact severity of the lesion during maximal blood flow (hyperemia). Hyperemia is induced by injecting products such as adenosine or papaverine. A pullback of the pressure wire is performed, and pressures are recorded across the vessel.

FFR is then 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). <sup>(16)</sup>

### ***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. <sup>(2)</sup>

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

### ***The Development of FFR-CT as a Technology*** <sup>(17,18,19,20,21)</sup>

Fractional Flow Reserve (FFR) is the ratio of baseline coronary flow to coronary flow during maximal hyperemia. Its use in the cardiac catheterization laboratory has successfully demonstrated utility in the quantitation of intracoronary flow dynamics secondary to lesional and microvasculature conditions. This technology has proven helpful in evaluating individual patients, with respect to prognostication of coronary artery disease and decisions regarding the appropriateness of coronary revascularization.

### ***Definitions***

- CCTA has shown utility in the evaluation of patients with stable chest pain, typically intermediate pretest probability, warranting non-invasive evaluation <sup>(15,22,23)</sup>, as well as in low-risk emergency department scenarios <sup>(24)</sup>
- Fractional flow reserve using CCTA seeks to provide an estimation of FFR by non-invasive methodology. Following assessment of quality CCTA images, in the

appropriate subsets of patients with coronary stenoses, the technology makes mathematical assumptions to simulate maximal hyperemia and calculates an estimation of FFR (fractional flow reserve) for those coronary vessels with lesions, based upon the principles of fluid mechanics inherent to the Navier-Stokes Theorem. (16,25)

- Quantitative estimation of coronary lesional hemodynamic severity using FFR<sub>CT</sub> might enable deferral of invasive coronary arteriography when values are above 0.80, since such lesions would not warrant revascularization. (11)
- FFR<sub>CT</sub> measurements appear reproducible (26), with initial data demonstrating a strong correlation to invasive FFR, resulting in a high diagnostic performance (27). Invasive FFR has excellent reproducibility (28) and a demonstrated track record of favorable outcomes when used in the selection of patients and vessels requiring PCI (17,18,20). Evidence suggests that FFR<sub>CT</sub> might be a better predictor of revascularization or adverse events than severe stenosis alone on CCTA (29) and that a negative FFR<sub>CT</sub> in the evaluation of chest pain results in lower revascularization rates and lower cardiovascular death and MI at 1 year follow-up. (30)
- The FFR<sub>CT</sub> data to date provides no evidence showing that revascularization based upon FFR<sub>CT</sub> improves clinical outcomes over invasive angiographic assessment.
- Current revascularization guidelines do not advocate FFR<sub>CT</sub> as a surrogate for invasive FFR, although, those guidelines refer to FFR<sub>CT</sub> as an “emerging technology”. (31)

## Acronyms / Abbreviations

BMI: Body Mass Index

CCTA: Coronary Computerized Tomographic Angiography

FFR: Fractional Flow Reserve

FFR<sub>CT</sub>: Fractional Flow Reserve derived noninvasively from CCTA

ICA: Invasive Coronary Arteriography

MI: Myocardial Infarction

NPV: Negative Predictive Value

PCI: Percutaneous Coronary Intervention

VSD: Ventricular Septal Defect

## POLICY HISTORY

### Summary

Date	Summary
February 2024	<ul style="list-style-type: none"> <li>• Formatting change</li> <li>• Addition of clinical reasoning statement with AUC scoring described</li> <li>• AUC scores added to bullet points</li> <li>• References updated</li> </ul>





Date	Summary
April 2023	<ul style="list-style-type: none"><li data-bbox="555 360 1378 416">• Added statement on clinical indications not addressed in this guideline</li></ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### **Committee**

**Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee**

#### **Disclaimer**

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# EVOLENT CLINICAL GUIDELINE 320 FOR CARDIAC RESYNCHRONIZATION THERAPY

<b>Guideline or Policy Number:</b> Evolut_CG_320	<b><u>Applicable Codes</u></b>	
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<b>Original Date:</b> February 2013	<b>Last Revised Date:</b> February 2024	<b>Implementation Date:</b> January 2025

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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.*

### 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).<sup>(1,2,3)</sup>

## INDICATIONS FOR CARDIOMYOPATHY

**NOTE:** The following indications only apply to patients:

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

### ***Class I Through Class IV*** <sup>(1,2,4)</sup>

- Ischemic cardiomyopathy, LVEF  $\leq$  30%, QRS  $\geq$  150, LBBB, Sinus Rhythm (**AUC 7-9**)

### ***Class II Through Class IV*** <sup>(1,2,4)</sup>

- Ischemic and non-ischemic cardiomyopathy, LVEF  $\leq$  35%, QRS  $\geq$  120ms, LBBB, Sinus Rhythm (**AUC 7-9**)
- Nonobstructive HCM, LVEF  $<$  50%, LBBB, CRT therapy for symptom reduction

### ***Class III Through Class IV*** <sup>(1,5)</sup>

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

### ***Special Situations: Independent/Regardless of NYHA Heart Failure Class***

- Patients with an indication for ventricular pacing and high degree AV block or are expected to be paced more than 40% of the time; this includes patients with Atrial fibrillation <sup>(1,5)</sup>
- 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
- 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 <sup>(4)</sup>
- As CRT has not been studied in ATTR-CM, those with HFrEF should follow guidelines for Class II-Class IV indications

### ***Not Indicated***

- NYHA class I and non-LBBB pattern with QRS duration  $<$  150 ms, <sup>(1,2)</sup> except as in Special Situations section above
- Comorbidities and/or frailty expected to limit survival with good functional capacity to  $<$ 1 year <sup>(6)</sup>
- 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

## **INDICATIONS FOR ADULT CONGENITAL HEART DISEASE**

### ***Class I Through Class IV***

- Systemic ventricle with any EF (not restricted), intrinsic narrow QRS complex, and undergoing new device placement or replacement with anticipated requirement for significant ( $>$  40%) ventricular pacing (**AUC 7-8**). <sup>(1,6)</sup>



### ***Class II Through Class IV***

- Systemic LV EF  $\leq$  35%, sinus rhythm and wide QRS complex  $\geq$  130 ms <sup>(6)</sup>
- Any CHD, wide QRS complex  $\geq$  150 ms due to a complete RBBB, with a severe sub-pulmonary RV dysfunction and dilatation despite interventions to decrease RV volume overload <sup>(6)</sup>

### ***Class IV***

- Severe ventricular dysfunction, and would otherwise be candidates for heart transplantation or mechanical circulatory support <sup>(6)</sup>

### ***Not Indicated***

- Patients whose co-morbidities and/or frailty limit survival with good functional capacity to  $<$  1 year <sup>(6)</sup>

## **INDICATIONS FOR CRT**

- As the appropriate pacing modality in special situations with  $<$  3 months of GDMT <sup>(1,7)</sup>
- Criteria are met for a non-elective implantable cardioverter defibrillator (ICD) or pacemaker and based upon 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.

## **CODING AND STANDARDS**

### **Coding**

#### ***CPT Codes***

33221, 33224, 33225, 33231

## Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

## BACKGROUND

### Overview

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

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 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. <sup>(1)</sup>
- GDMT should have been in place continuously for at least 3 months and recovery of LVEF from myocardial infarction (40 days) if no intervening revascularization or > 3 months if revascularization was performed. Reversible causes (e.g., ischemia) should be excluded. <sup>(2,4)</sup>
- The patient should have expected survival with reasonably good functional status for more than 1 year. <sup>(2,6)</sup>

### Definitions

#### **NYHA Class Definitions** <sup>(1,3)</sup>

- 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 (2)***

- 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 (4)***

- 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***

- 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  $\geq 30$  ml/min/1.73m<sup>2</sup> and K<sup>+</sup> < 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.

## Acronyms/Abbreviations

ACE-I: Angiotensin converting enzyme inhibitor  
 ARB: Angiotensin receptor blocker  
 ARNI: Combined angiotensin receptor inhibitor and neprilysin inhibitor  
 AV: Atrioventricular  
 CAD: Coronary artery disease, same as ischemic heart disease  
 CHD: Congenital heart disease  
 CHF: Congestive heart failure  
 CRT: Cardiac resynchronization therapy (also known as biventricular pacing)  
 CRT-D: Cardiac resynchronization therapy defibrillator  
 ECG: Electrocardiogram  
 EF: Ejection Fraction  
 eGFR: Estimated glomerular filtration rate  
 EPS: Electrophysiologic Study  
 GDMT: Guideline-Directed Medical Therapy  
 HCM: Hypertrophic Cardiomyopathy  
 HF: Heart failure  
 HFrEF: Heart failure with reduced ejection fraction  
 HV: His-ventricular  
 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  
 SND: Sinus node dysfunction  
 SR: Sinus rhythm  
 STEMI: ST-Elevation Myocardial Infarction  
 VT: Ventricular tachycardia

## POLICY HISTORY

### Summary

Date	Summary
February 2024	<ul style="list-style-type: none"> <li>● Added AUC Scoring to Cardiac Guidelines from published Societies. When an AUC score was not published by a Society we assigned an AUC score of 6 based upon AUC scoring standards – this has been explained in Clinical Reasoning</li> <li>● No other substantive changes were made</li> </ul>



Date	Summary
April 2023	<ul style="list-style-type: none"><li>● Added additional statement on atrial fibrillation</li><li>● Added statement on ATTR</li><li>● Added additional contraindication for patients with LVAD</li><li>● Removed indication for Class I and CRT</li><li>● Combined Class II- IV indications</li><li>● Removed EF value for requirement for pacemaker</li><li>● Added statement on clinical indications not addressed in this guideline</li></ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### Committee

Reviewed / Approved by Evolent Specialty 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. 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.*

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# EVOLENT CLINICAL GUIDELINE 321 FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

<b>Guideline or Policy Number:</b> Evolent_CG_321	<b><u>Applicable Codes</u></b>	
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<b>Original Date:</b> February 2013	<b>Last Revised Date:</b> February 2024	<b>Implementation Date:</b> January 2025

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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.*

### Purpose

Indications for determining medical necessity for an implantable cardiac defibrillator (ICD). Implantable cardioverter defibrillators (ICDs) are indicated for the treatment of life-threatening ventricular tachycardia and ventricular fibrillation. All indications are predicated on a meaningful life expectancy of greater than one year if the ICD is implanted.

### 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. <sup>(1,2,3,4,5)</sup>

## INDICATIONS FOR ICD INSERTION

### Ischemic Heart Disease (CAD) <sup>(6,7,8)</sup>

#### ***Primary Prevention of SCD/Prophylactic ICD Implantation***

- LVEF  $\leq$  35% due to nonischemic or ischemic heart disease and **NYHA** class II or III, despite **GDMT**, and at least 40 days post-MI (**AUC 9**)

- LVEF  $\leq$  30% due to ischemic heart disease, **NYHA** class I, **GDMT**, and at least 40 days post-MI (**AUC 8**)
- LVEF  $\leq$  40% with prior MI, NSVT, and inducible sustained VT or VF at electrophysiological testing

### ***Secondary Prevention of SCD***

- Patients with documented VF, hemodynamically unstable VT, or sustained VT, after exclusion of reversible causes (**AUC 9**)
- Syncope of undetermined origin, with inducible VF or sustained VT at electrophysiological study (**AUC 9**)
- Syncope of undetermined origin, with EF  $\leq$  35% (**AUC 8-9**)

## **Nonischemic Cardiomyopathy (NICM) <sup>(6)</sup>**

### ***Primary Prevention of SCD/Prophylactic ICD Implantation***

- Lamin A/C gene mutation, with  $\geq$  2 risk factors from the following: NSVT, LVEF  $<$  45%, male sex, missense mutation
- LVEF  $\leq$  35% and **NYHA** functional Class II or III, despite at least 3 months of **GDMT**
- **NOTE:** LVEF  $\leq$  35% and **NYHA** functional Class I despite at least 3 months of **GDMT** may be considered

### ***Secondary Prevention of SCD***

- Patients with documented VF, hemodynamically unstable VT, or sustained VT, after exclusion of reversible causes
- LVEF  $\leq$  50% with unexplained syncope presumed to be due to VA who do not meet indications for primary prevention ICD implantation

## **Advanced Heart Failure & Transplantation <sup>(6,7,8)</sup>**

- In non-hospitalized patients with **NYHA** class IV who are candidates for cardiac transplantation or left ventricular assist device (LVAD)
- In a patient with an LVAD, sustained ventricular arrhythmias
- In **NYHA** ambulatory class IV, with appropriate indications for CRT

## Myocardial Diseases

### ***Hypertrophic Cardiomyopathy (HCM)*** <sup>(6,8,9,10,11)</sup>

- Previously documented cardiac arrest or sustained VT
- Adult patients with HCM with at least 1 risk factor for SCD as follows:
  - Sudden death attributable to HCM in at least 1 first-degree relative who is  $\leq 50$  years of age
  - LVH  $\geq 30$  mm
  - At least 1 recent (within 5 years) episode of syncope suspected by history to be arrhythmic (unlikely neurocardiogenic (vasovagal), especially occurring within 6 months of evaluation
  - LV apical aneurysm
  - LV systolic dysfunction (EF  $< 50\%$ )
  - Pediatric patients with HCM with at least 1 risk factor for SCD as follows:
    - Unexplained syncope
    - LVH  $\geq 30$  mm
    - Nonsustained VT
    - Family history of HCM-related SCD

### ***Cardiac Sarcoidosis***

With one of the following:<sup>(6,8,9)</sup>

- Cardiac arrest or documented sustained VT
- LVEF  $\leq 35\%$  (**AUC 8**)
- LVEF  $> 35\%$  with inducible sustained VA at electrophysiological testing
- Syncope and/or scar on CMR or PET
- Requires a permanent pacemaker

### ***Neuromuscular Disorders***

Including but not limited to Duchenne, Becker, Limb-girdle type 1B, Limb-girdle type 2C-2F, Limb-girdle type 2I, Myotonic type 1, Myotonic type 2, Emery-Dreifuss, or Facioscapulohumeral Muscular Dystrophy with one of the following:<sup>(6,8)</sup>

- Primary and secondary prevention, with same indications as for NICM

- Emery-Dreifuss or limb-girdle type I-B muscular dystrophy with progressive cardiac involvement

### ***Arrhythmogenic Right Ventricular Cardiomyopathy***

With at least one of the following risk factors for SCD:<sup>(6,9,10)</sup>

- Resuscitated sudden cardiac arrest
- Sustained VT
- Right or left ventricular systolic dysfunction with an EF  $\leq$  35%
- Syncope with documented or presumed ventricular arrhythmia

## **Channelopathies**

### ***Congenital Long QT Syndrome***

With one of the following **(AUC 9)** :<sup>(6,8,10)</sup>

- Sudden cardiac arrest
- Sustained VT or recurrent syncope when beta blocker is ineffective or not tolerated
- QTc > 500 ms on a beta blocker
- Strong family history of SCD
- High risk genotype

### ***Brugada Syndrome and Spontaneous Type 1 Brugada Echocardiographic Pattern***

With one of the following **(AUC 9)**:<sup>(6,8,10)</sup>

- Cardiac arrest
- Documented sustained VA
- Syncope presumed to be due to VA

### ***Catecholaminergic Polymorphic VT***

With one of the following **(AUC 9)**:<sup>(6,7,10)</sup>

- Sudden cardiac arrest
- Syncope or sustained VT

- Inducible VT or VF

### ***Early Repolarization ("J-wave Syndrome") or Short QT Syndrome***

With one of the following (AUC 9): <sup>(6,8)</sup>

- Cardiac arrest
- Sustained VA

### ***Idiopathic Polymorphic VT/VF*** <sup>(6)</sup>

- Cardiac arrest due to polymorphic VT or VF

### **Adult & Pediatric Congenital Heart Disease (CHD)** <sup>(6,7,8,9,11)</sup>

- Cardiac arrest due to VF or VT, or unstable VT, after exclusion of a reversible etiology
- Systemic LVEF  $\leq 35\%$ , biventricular physiology, and NYHA class II or III on GDMT
- Tetralogy of Fallot with one of the following:
  - Spontaneous sustained VT
  - Inducible VF or sustained VT
  - $\geq 1$  risk from the following list:
    - Prior palliative systemic to pulmonary shunts
    - Unexplained syncope
    - Frequent PVCs (Premature Ventricular Contractions)
    - Atrial tachycardia
    - Left ventricular dysfunction or diastolic dysfunction
    - NSVT
    - QRS duration  $\geq 180$  ms
    - Dilated right ventricle
    - Residual pulmonary regurgitation or stenosis
    - RV Hypertension
- Single or systemic RVEF  $< 35\%$ , in the presence of an additional risk factor such as:
  - NSVT
  - Unexplained syncope

- NYHA class II or III, despite GDMT
- QRS duration  $\geq$  140 ms
- Severe systemic AV valve regurgitation
- Syncope of unknown origin in the presence of either at least moderate ventricular dysfunction or marked hypertrophy or inducible sustained VT or VF
- Syncope and moderate or severe complexity CHD, with high clinical suspicion of VA
- Non-hospitalized patients with CHD awaiting heart transplant
- Left ventricular non-compaction that meets same indications as NICM, including a familial history of SCD

## ICD With an Appropriate Pacing Modality in Special Situations <sup>(6,7,12)</sup>

**NOTE: With these ICD indications, CRT would sometimes be the appropriate pacing modality. CRT is likely to be the appropriate modality with anticipated requirement for significant (> 40%) ventricular pacing**

- ICD criteria met, and elevated troponin is deemed not due to a myocardial infarction
- ICD criteria met, except for myocardial infarction within 40 days or revascularization within 3 months, but a non-elective permanent pacemaker (new or replacement) is required, and recovery of left ventricular function to LVEF > 35% is uncertain or not expected\*
- ICD criteria met, except NICM or ischemic cardiomyopathy has not had 3 months' time for LVEF to improve on medical therapy, a non-elective permanent pacemaker is required, and recovery of LVEF is uncertain or not expected\*
- Patient met primary prevention criteria for an ICD prior to coronary revascularization, and it is unlikely that LVEF will recover to > 35% despite a 90-day wait

**\* These indications avoid a second implantation procedure within less than 3 months**

## CODING AND STANDARDS

### Coding

#### *CPT Codes*

33230, 33240, 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 type="checkbox"/>	Medicare Advantage

## BACKGROUND

The implantable cardioverter defibrillator (ICD) has become valuable in the management of patients with ventricular arrhythmias (VA) capable of causing syncope, cardiac arrest, and sudden cardiac death (SCD). An ICD system includes a pulse generator and one or more leads. ICDs are indicated both for patients who have survived life threatening rhythm disturbances (secondary prevention) and for those who are at risk for them (primary prevention).

Patient eligibility for an ICD presumes all the following:

- Anticipated reasonable quality of life for  $\geq$  1-year post implantation
- Patient’s ability to live with a shock-delivering device that requires management
- Absence of a completely reversible cause that led to VA for which an ICD is being considered
- Completion of  $\geq$  3 months of guideline-directed medical therapy (GDMT) for heart failure (HF), unless an intervening indication for pacemaker implantation arises
- ICD indications are present in most scenarios in which cardiac resynchronization therapy (CRT) is appropriate

Guidelines for the pediatric population are extrapolated from the adult population due to a lack of relevant trials.

## NYHA Class Definitions <sup>(7,13)</sup>

- 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

## Guideline Directed (or Optimal) Medical Therapy in Heart Failure <sup>(14)</sup>

- 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***

- 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  $\geq 30$  ml/min/1.73m<sup>2</sup> and K<sup>+</sup> < 5.0, NYHA class II-IV
- Normal serum sodium and potassium
- Not required for consideration of ICD: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm. Ivabradine listed as a class IIa recommendation, while others are class I recommendations. CRT trials antedated routine use of Ivabradine.

## Acronyms / Abbreviations

ACE-I: Angiotensin converting enzyme inhibitor  
ARNI: Combined angiotensin receptor inhibitor and neprilysin inhibitor  
ARVD/C: Arrhythmogenic right ventricular dysplasia/cardiomyopathy  
AV: Atrioventricular  
CAD: Coronary artery disease, same as ischemic heart disease  
CHD: Congenital heart disease  
CHF: Congestive heart failure  
CRT: Cardiac resynchronization therapy  
CRT-D: Cardiac resynchronization therapy ICD system  
DCM: Dilated cardiomyopathy  
ECG: Electrocardiogram  
EF: Ejection fraction  
EPS: Electrophysiologic Study  
GDMT: Guideline-Directed Medical Therapy  
HCM: Hypertrophic cardiomyopathy  
HF: Heart failure  
HV: His-ventricle  
ICD: Implantable cardioverter-defibrillator  
LBBB: Left bundle-branch block



LV: Left ventricular/left ventricle  
 LVAD: Left ventricular assist device, mechanical heart  
 LVEF: Left ventricular ejection fraction  
 LVH: Left ventricular hypertrophy  
 MI: Myocardial infarction  
 ms: Milliseconds  
 NICM: Nonischemic cardiomyopathy  
 NSVT: Nonsustained ventricular tachycardia  
 NYHA: New York Heart Association  
 PET: Positron emission tomography  
 PVC: Premature Ventricular Contraction  
 RV: Right ventricular/right ventricle  
 RVEF: Right ventricular ejection fraction  
 SCD: Sudden Cardiac Death  
 STEMI: ST-elevation myocardial infarction  
 SND: Sinus node dysfunction  
 VT: Ventricular tachycardia  
 VF: Ventricular fibrillation

## POLICY HISTORY

### Summary

Date	Summary
February 2024	<ul style="list-style-type: none"> <li>Added AUC Scoring to Cardiac Guidelines from published Societies. When an AUC score was not published by a Society, we assigned an AUC score of 6 based upon AUC scoring standards – this has been explained in Clinical Reasoning</li> </ul>
April 2023	<ul style="list-style-type: none"> <li>Added nonischemic CM indication for EF <math>\leq</math> 35% and removed statement about requirement of 90-day post revascularization</li> <li>Added statement on clinical indications not addressed in this guideline</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

**Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee**



## **Disclaimer**

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# EVOLENT CLINICAL GUIDELINE 322 FOR PACEMAKER

<b>Guideline or Policy Number:</b> Evolut_CG_322	<b><u>Applicable Codes</u></b>	
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<b>Original Date:</b> February 2013	<b>Last Revised Date:</b> March 2024	<b>Implementation Date:</b> January 2025

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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.*

### 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. <sup>(1,2,3,4,5)</sup>

## INDICATIONS FOR PACEMAKERS IN ADULTS

Excludes conditions that are expected to resolve.

### Sinus Node Dysfunction (SND)

- Documented symptomatic sinus bradycardia, including frequent sinus pauses <sup>(6,7)</sup>
- 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 (Holter/MCOT/Electrocardiography (ECG)) recording data <sup>(6,7)</sup>
- Symptomatic sinus bradycardia that results from required guideline-directed medical therapy (GDMT) for which there is no alternative treatment <sup>(6,7)</sup>
- Heart rate less than 40 while awake, even without definite association with significant symptoms consistent with bradycardia <sup>(6)</sup>
- Tachycardia-bradycardia syndrome and symptoms attributable to bradycardia <sup>(7,8)</sup>
- Syncope of unexplained origin with clinically significant SND, either documented or provoked in electrophysiologic study (EPS) <sup>(6)</sup>

### Acquired Atrioventricular (AV) Block

#### *First-Degree AV Block*

- Marked first-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block <sup>(7)</sup>
- First-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise <sup>(7)</sup>

#### *Second Degree AV Block (Mobitz Types I and II)*

- Marked second-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block <sup>(6,7)</sup>
- Second-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise <sup>(6)</sup>
- Second-degree Mobitz Type II AV block regardless of symptoms <sup>(6,7)</sup>
- Advanced second-degree AV block <sup>(6)</sup>
- Second-degree AV block associated with a wide QRS, or EPS-documented intra- or infra-His conduction <sup>(6)</sup>



- Symptomatic bradycardia associated with second-degree AV block, either Mobitz I or II <sup>(6)</sup>

### **Third-Degree/Complete AV Block**

- Third-degree (complete) AV block, intermittent or persistent, regardless of symptoms <sup>(6)</sup>
- High-grade AV block, regardless of symptoms <sup>(7)</sup>

### **AF/Other**

- Atrial fibrillation while awake, with pauses  $\geq 5$  seconds, or symptomatic bradycardia <sup>(6)</sup>
- In sinus rhythm (with AV block) while awake, pauses  $\geq 3$  seconds or heart rates less than 40 beats per minute or an escape rhythm below the AV node <sup>(6)</sup>
- Following catheter ablation of the AV junction <sup>(6)</sup>
- Symptomatic AV block that results from required medical therapy for which there is no alternative treatment <sup>(6,7)</sup>
- Exercise-induced second- or third-degree AV block without myocardial ischemia <sup>(6,7)</sup>

### **Neuromuscular Disorders**

- Marked first-degree or higher AV block, or an H-V 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 <sup>(6,7)</sup>

### **Chronic Fascicular (Including Any of RBBB, LBBB, LAHB, LPHB) Block**

- Alternating bundle-branch block <sup>(6,7)</sup>
- Syncope of unexplained origin when other likely causes have been excluded, specifically ventricular tachycardia <sup>(6)</sup>
- Syncope and bundle branch block with an HV interval  $\geq 70$  ms, or evidence of infranodal block at EPS <sup>(7)</sup>
- Incidental findings at EPS study of an H-V interval  $\geq 100$  milliseconds, or non-physiological, pacing-induced infra-His block in asymptomatic patients <sup>(6)</sup>

## **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<sup>(6)</sup>, or AV block, or  $\geq 50$  mmHg drop in systolic BP
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole)  $\geq 3$  seconds<sup>(6)</sup>
- Recurrent syncope and asystole  $\geq 3$  seconds with syncope or  $\geq 6$  seconds without symptoms or with presyncope, documented by ECG recording data<sup>(9,10)</sup>

## **Pacing to Terminate or Prevent Tachycardia**

- Symptomatic recurrent supraventricular tachycardia documented to be terminated by pacing in the setting of failed catheter ablation and/or drug treatment<sup>(6)</sup>
- Prevention of pause-dependent ventricular tachycardia (VT)<sup>(6)</sup>

## **Recommendations for Permanent Pacing in Patients with Hypertrophic Cardiomyopathy (HCM)**

- Permanent pacing may be considered in medically refractory symptomatic patients with HCM and significant resting or provoked LV outflow tract obstruction

## **Recommendations for Leadless Pacemaker Include<sup>(11,12)</sup>**

- Patients with bradycardia and need only single chamber (RV) pacing in VVI or VVIR mode:
  - Symptomatic paroxysmal or permanent high-grade AV block in the presence of atrial fibrillation (AF).
  - Symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.
  - Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.
  - Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity

## INDICATIONS FOR CONGENITAL HEART DISEASE PACING (PEDIATRIC AND ADULT)

### Children, Adolescents (<19 Years), and Adult Patients with Congenital Heart Disease (CHD)

#### *Sinus Node Dysfunction*

- SND with symptomatic age- and activity-inappropriate bradycardia <sup>(7)</sup>
- Sinus bradycardia with complex CHD AND a resting heart rate < 40 bpm **OR** pauses in ventricular rate > 3 seconds <sup>(13)</sup>
- 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*

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output <sup>(8)</sup>
- Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction <sup>(7)</sup>
- 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 <sup>(7)</sup>
- 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 <sup>(7,8)</sup>
- Adults with congenital complete AV block, regardless of symptoms <sup>(7)</sup>
- 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

### **Scenarios in which Pacemakers are Not Indicated** <sup>(8,14)</sup>

- SND in patients that are asymptomatic, or symptoms occur without documented bradycardia
- Asymptomatic first-degree AV block or Mobitz I second-degree AV block with a narrow QRS
- Asymptomatic fascicular block (Including any of RBBB, LBBB, LAHB, LPHB)
- Asymptomatic bifascicular block (RBBB/LAHB or RBBB/LPHB) with or without first-degree AVB where a higher degree of heart block has not been demonstrated
- Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms
- Asymptomatic bifascicular block (RBBB/LAHB or RBBB/LPHB) with or without first-degree AVB after surgery for CHD without prior transient complete AV block

## **CODING AND STANDARDS**

### **Coding**

#### **CPT Codes**

33206, 33207, 33208, 33212, 33213

### **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 type="checkbox"/>	Medicare Advantage

## **BACKGROUND**

A pacemaker system is composed of a pulse generator and one or more leads. The pulse generator is implanted under the skin, usually below one of the collarbones (clavicles). It contains a battery, a microprocessor that governs timing and function, and a radio antenna to allow for noninvasive interrogation and reprogramming. The leads are insulated cables that conduct electricity from the pulse generator to the heart. Leads are most commonly inserted into a vein and then advanced under fluoroscopy (x-ray guidance) to within one or more heart chambers. The leads are fastened within the chambers to the heart muscle using either hooks or retractable/extendable screws, which are built into their tips. Timed electrical

impulses are delivered from the pulse generator via the leads to the heart, where stimulation results in heart muscle contraction.

## 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.<sup>(4)</sup>

**Appropriate Care - Median Score 7-9**

**May be Appropriate Care - Median Score 4-6**

**Rarely Appropriate Care - Median Score 1-3**

## Heart Block Definitions <sup>(6)</sup>

- 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

CHF: Congestive heart failure

CRT: Cardiac resynchronization therapy (same as biventricular pacing)

ECG: Electrocardiogram

EPS: Electrophysiologic Study

GDMT: Guideline-Directed Medical Therapy

HV: 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

## POLICY HISTORY

### Summary

Date	Summary
March 2024	<ul style="list-style-type: none"> <li>Added AUC Scoring to Cardiac Guidelines from published Societies. When an AUC score was not published by a Society, we assigned an AUC score of 6 based upon AUC scoring standards – this has been explained in Clinical Reasoning</li> </ul>
April 2023	<ul style="list-style-type: none"> <li>Additional statement on leadless pacemaker</li> <li>Added statement on clinical indications not addressed in this guideline</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### Committee

**Reviewed / Approved by Evolent Specialty 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. 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.*

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# EVOLENT CLINICAL GUIDELINE 067 FOR TRANSTHORACIC ECHOCARDIOGRAM

<b>Guideline or Policy Number:</b> Evolent_CG_067	<b><u>Applicable Codes</u></b>	
<p><i>"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc.</i></p> <p><b>© 2009 - 2025 Evolent. All rights Reserved.</b></p>		
<b>Original Date:</b> October 2009	<b>Last Revised Date:</b> June 2024	<b>Implementation Date:</b> January 2025

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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.*

### Purpose

Transthoracic echocardiography (TTE) uses ultrasound to image the structures of the heart providing 2-dimensional, cross-sectional images. The addition of Doppler ultrasound derives hemodynamic data from flow velocity versus time measurements, as well as from color-coded two-dimensional representations of flow velocities.

### 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. <sup>(1,2,3,4,5)</sup>

# INDICATIONS FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE) ADULT PATIENTS <sup>(6)</sup>

(Indications for pediatric patients follow this section)

## Evaluation of Cardiac Structure and Function

- When initial evaluation including history, physical examination, electrocardiogram (ECG), remote monitor or other testing suggests a cardiac etiology for symptoms, including but not limited to: **(AUC 9)** <sup>(7)</sup>
  - Chest pain when another study is not planned to evaluate
  - Shortness of breath
  - Palpitations
- Hypotension suggestive of cardiac etiology not due to other causes, such as: **(AUC 8)** <sup>(7)</sup>
  - Medications, dehydration, or infection
- ECG Abnormalities
  - Previously unevaluated pathological Q waves (in two contiguous leads) defined as the following:
    - 40 ms (1 mm) wide
    - > 2 mm deep
    - > 25% of depth of QRS complex
  - New left bundle branch block **(AUC 7)** <sup>(7)</sup>
    - New isolated RBBB is **not** an indication for TTE.
  - Symptomatic or asymptomatic patients with previously unevaluated left ventricular hypertrophy (i.e., concern for hypertrophic cardiomyopathy). **(AUC 9)** <sup>(7)</sup>

## Murmur or Click

- Initial evaluation when there is a reasonable suspicion for valvular or structural heart disease such as: **(AUC 9)** <sup>(8)</sup>
  - High grade  $\geq 3/6$ : Note that TTE can be approved for documented concern that murmur suggests a **specific valve pathology** (such as “aortic valve sclerosis/stenosis” or “mitral regurgitation”) **regardless of grade of murmur**
  - Holosystolic

- Continuous
- Diastolic

## Arrhythmias

- Frequent premature ventricular contractions (PVCs, greater than 30 per hour on remote monitoring or  $\geq 1$  PVC on 12 lead ECG) **(AUC 7)**<sup>(7)</sup>
  - Isolated premature atrial complexes (PACs) are not an indication for TTE.
- Sustained or nonsustained ventricular tachycardia (VT) or ventricular fibrillation (VF), or ventricular bigeminy **(AUC 9)**<sup>(7)</sup>
- New onset atrial fibrillation (as documented in MD notes and on ECG) which was not evaluated by a prior transthoracic echocardiogram (TTE) **(AUC 8)**<sup>(7)</sup>
- Initial evaluation of SVT seen on ECG or remote monitoring without other evidence of heart disease **(AUC 6)**<sup>(9)</sup>

## Syncope <sup>(8,10)</sup>

- History, physical examination, or electrocardiogram (ECG) consistent with a cardiac diagnosis known to cause presyncope or syncope, including but not limited to: **(AUC 9)**<sup>(7)</sup>
  - Structural heart disease (including but limited to):
    - Hypertrophic cardiomyopathy
    - Systolic heart failure
  - Exercise-induced syncope
- And not due to other causes such as:
  - Vaso-vagal syncope, neurogenic orthostatic syncope
  - Orthostasis related to medication or dehydration

## Perioperative Evaluation <sup>(11,12)</sup>

- Preoperative left ventricular function assessment in patients who are candidates for solid organ transplantation (can be done yearly prior to transplant) **(AUC 8)**<sup>(7)</sup>

## Pulmonary Hypertension

- Evaluation of suspected pulmonary hypertension including evaluation of right ventricular function and estimated pulmonary artery pressure **(AUC 9)** <sup>(7)</sup>
- Re-evaluation of known pulmonary hypertension if there is a change in clinical status or cardiac exam or a need to change medications <sup>(13)</sup> such as: **(AUC 8)** <sup>(7)</sup>
  - New chest pain
  - Worsening shortness of breath
  - Syncope
  - Increased murmur
  - Worsening rales on lung examination
- Initial evaluation of patients with pulmonary embolism to risk stratify and initiate appropriate therapy <sup>(14)</sup>
  - Repeat TTE can be approved for persistent dyspnea 3-6 months after PE <sup>(15)</sup> to evaluate for possible chronic thromboembolic pulmonary hypertension (CTEPH)
- Annual screening can be performed for pulmonary hypertension in patients with: <sup>(13,16)</sup>
  - Scleroderma
  - Portal hypertension (including evaluation prior to TIPS procedure)
  - Carriers of Bone Morphogenetic Protein Receptor 2 (BMP2) mutation
  - Sickle cell disease

## Known Valvular Heart Disease

### ***Symptomatic***

- ***New clinical signs and symptoms*** (SOB/fatigue) with known **mild** valvular heart disease or known **moderate to severe** valvular heart disease. **(AUC 9)** <sup>(8)</sup>

## Native Valvular Stenosis <sup>(8)</sup>

### ***Asymptomatic (Routine re-evaluation)***

- Routine surveillance ( $\geq 3$  yrs.) of bicuspid aortic valve, or mild valvular stenosis
- Re-evaluation ( $\geq 1$  yr.) of moderate stenosis
- Re-evaluation of severe aortic stenosis (AS) every 6 - 12 months
- Re-evaluation after control of hypertension in patients with low flow/low gradient severe aortic stenosis

## **Native Valvular Regurgitation (8,17,18)**

### ***Asymptomatic (Routine re-evaluation)***

- ≥ 3 yrs. of mild valvular regurgitation **(AUC 8)** <sup>(8)</sup>
- ≥ 1 yr. of moderate valvular regurgitation
- Asymptomatic patient every 6 - 12 months with severe valvular regurgitation

## **Prosthetic Valves/Native Valve Repair (19)**

- Initial evaluation of prosthetic valve or native valve repair, for establishment of baseline, typically 6 weeks to 3 months postoperative and: **(AUC 9)** <sup>(8)</sup>
  - **Routine surveillance (Asymptomatic)**
    - Surgical bioprosthetic valve
      - Every 3 years after surgery **(AUC 7)** <sup>(8)</sup>
    - Surgical mechanical valve
      - 10 years postoperatively and annually thereafter **(AUC 9)** <sup>(8)</sup>
    - Surgical mitral valve repair
      - 1-year post-op and then every 2-3 years **(AUC 8)** <sup>(8)</sup>
- Evaluation of prosthetic valve or native valve repair with suspected dysfunction, with symptoms including but not limited to: **(AUC 9)** <sup>(8)</sup>
  - Chest pain
  - Shortness of breath
  - New or Increased murmur on heart examination
  - New rales on lung examination
  - Elevated jugular venous pressure on exam

## **Transcatheter Heart Interventions**

### ***Transcatheter Aortic Valve Replacement (TAVR)*** <sup>(8,20,21)</sup>

- Pre TAVR evaluation
- Post TAVR at 30 days (6 weeks to 3 months also acceptable) and annually **(AUC 8)** <sup>(8)</sup>
- Assessment post TAVR when there is suspicion of valvular dysfunction, including but not limited to: **(AUC 8)** <sup>(8)</sup>
  - Chest pain



- Shortness of breath
- New or increased murmur on heart examination
- CVA post TAVR **(AUC 7)**
- Assessment of stroke post TAVR **(AUC 7)**<sup>(8)</sup>

### ***Percutaneous Mitral Valve Repair (PMVR)*** <sup>(8,17,20)</sup>

- Pre-procedure evaluation **(AUC 8)**<sup>(8)</sup>
- Reassessment for degree of MR and left ventricular function (1, 6 months, and annually) **(AUC 9)**<sup>(7)</sup>
- Assessment post TMVR when there is suspicion of valvular dysfunction, including but not limited to: **(AUC 8)**<sup>(8)</sup>
  - Chest pain
  - Shortness of breath
  - New or increased murmur on heart examination
  - CVA post TMVR

### ***Closure of PFO or ASD*** <sup>(7)</sup>

- Pre-procedure evaluation **(AUC 9)**<sup>(22)</sup>
- Routine follow-up post procedure for device position and integrity (see **Table 2**) **(AUC 9)**<sup>(22)</sup>
- Evaluation for clinical concern for infection, malposition, embolization, or persistent shunt **(AUC 9)**<sup>(22)</sup>
- Routine surveillance of an asymptomatic patient with a PFO is **not** indicated<sup>(22)</sup>

### ***Left Atrial Appendage (LAA) Occlusion*** <sup>(7)</sup>

- Pre-procedure evaluation **(AUC 8)**<sup>(7)</sup>

### **Pericardial Disease** <sup>(7,14,23,24)</sup>

- Suspected pericarditis or pericardial effusion **(AUC 9)**<sup>(7)</sup>
- Re-evaluation of a significant known pericardial effusion when findings would lead to change in management **(AUC 7)**<sup>(7)</sup>

- Suspected pericardial constriction or reevaluation of status when management would be changed

## Evaluation of Cardiac Source of Emboli or Cardiac Mass <sup>(8)</sup>

- Embolic source in patients with recent transient ischemic attack (TIA), stroke, or peripheral vascular emboli **(AUC 9)** <sup>(7)</sup>
- Evaluation of intracardiac mass or re-evaluation of known mass. No echo performed within the last three months <sup>(25)</sup> **(AUC 8)** <sup>(7)</sup>

## Infective Endocarditis (Native or Prosthetic Valves) <sup>(8,20,26)</sup>

- Initial evaluation of suspected infective endocarditis with positive blood cultures or a new murmur **(AUC 9)** <sup>(8)</sup>
- Re-evaluation
  - Infective endocarditis with, but not limited to: **(AUC 9)** <sup>(8)</sup>
    - Changing cardiac murmur
    - Evidence of embolic phenomena such as TIA or CVA
    - New chest pain, shortness of breath, or syncope
    - A need to change medications due to ongoing fever, positive blood cultures, or evidence of new AV block on ECG
  - Infective endocarditis at high risk of progression or complication (extensive infective tissue/large vegetation, or staphylococcal, enterococcal, or fungal infections) **(AUC 7)** <sup>(8)</sup>
- At completion of antimicrobial therapy and serial examinations at 1, 3, 6, and 12 months during the subsequent year <sup>(26)</sup>

## Thoracic Aortic Disease <sup>(27,28,29,30,31,32)</sup>

In the absence of recent computed tomography (CT) or cardiovascular magnetic resonance (CMR), which are preferred for imaging beyond the proximal ascending aorta

- Screening of first-degree relatives of individuals with:
  - Thoracic aortic aneurysm (defined as  $\geq 50\%$  above normal) or dissection
  - Bicuspid aortic valve
  - Presence of an aortopathic syndrome (i.e., Marfan's, Ehlers-Danlos, Loeys-Dietz, or Turner's)

- If one or more first-degree relatives of a patient with a known thoracic aortic aneurysm or dissection, have thoracic aortic dilatation, aneurysm, or dissection; then imaging of 2<sup>nd</sup> degree relatives is reasonable
- Six-month follow-up after initial finding of a dilated thoracic aorta
- Annual follow-up of enlarged thoracic aorta that is above top normal for age, gender, and body surface area
- Biannual (twice/year) follow-up of enlarged aortic root  $\geq 4.5$  cm or showing growth rate  $\geq 0.5$  cm in one year or  $\geq 0.3$ cm per year in 2 consecutive years for sporadic aneurysms and  $\geq 0.3$ cm in 1 year for heritable thoracic aortic disease or bicuspid aortic valve <sup>(28)</sup>
- Evaluation of the ascending aorta in known or suspected connective tissue disease or genetic conditions that predispose to aortic aneurysm or dissection (e.g., Marfan syndrome, Ehlers-Danlos or Loeys-Dietz syndromes) at time of diagnosis and 6 months thereafter for growth rate assessment, followed by annual imaging, or biannual (twice yearly) if diameter  $\geq 4.5$  or expanding  $\geq 0.3$  cm/yr. **(AUC 8)** <sup>(7)</sup>
- Turner's Syndrome:
  - Baseline evaluation at the time of diagnosis to assess for bicuspid aortic valve, coarctation of the aorta, aortic root and ascending aortic dilatation and other congenital defects.
  - Surveillance imaging (initial imaging normal and no additional risk factors for dissection such as HTN or bicuspid aortic valve):
    - Children: every 5 years
    - Adults: every 10 years
    - Prior to planned pregnancy
    - Annual imaging can be approved if an abnormality is found (such as bicuspid aortic valve)
- Re-evaluation of known ascending aortic dilation or history of aortic dissection with one of the following:
  - New chest pain
  - Shortness of breath
  - Syncope
  - TIA or CVA
  - New or increased aortic valve murmur on clinical examination
  - New rales on lung examination or increased jugular venous pressure
  - **OR** when findings would lead to referral to a procedure or surgery
- Follow-up of aortic disease when there has been no surgical intervention:
  - Acute dissection: 1 month, 6 months, 12 months, then annually

- Chronic dissection: annually
- Follow-up thoracic aortic aneurysm repair: chest CTA or chest MRA are the recommended surveillance imaging modalities.
- Follow-up post either: Root repair or AVR plus ascending aortic root/arch repair: baseline post-op, then annually
- Evaluation of sinus of Valsalva aneurysms and associated shunting secondary to rupture.<sup>(32)</sup>

## Hypertension (HTN) (Adult)<sup>(7,28)</sup>

- Initial evaluation of suspected hypertensive heart disease including but not limited to the following:
  - Left ventricular hypertrophy on ECG
  - Cardiomegaly
  - Evidence of clinical heart failure
- Initial evaluation of uncontrolled, resistant HTN without symptoms on three or more anti-hypertensive drugs.

## Hypertension (HTN) (Pediatric)<sup>(33)</sup>

**(AUC 9)**<sup>(34)</sup>

- Initial evaluation at time of consideration of pharmacologic treatment of HTN
- Re-evaluation at 6–12-month intervals for:
  - Persistent HTN despite treatment
  - Concentric LVH on prior study
  - Reduced LVEF on prior study
- Re-evaluation of patients without LVH on initial evaluation can have TTE annually for:
  - Stage 2 HTN (BP  $\geq$ 140/90 mmHg)
  - Secondary HTN
  - Chronic stage 1 HTN (BP between 130/80 mmHg and 139/89 mmHg) incompletely treated, including drug resistance and noncompliance

## Heart Failure<sup>(7,35,36,37)</sup>

- Initial evaluation of suspected HF (systolic or diastolic) based on symptoms, signs, or abnormal test result, including but not limited to: **(AUC 9)**<sup>(7)</sup>

- Dyspnea
- Orthopnea
- Paroxysmal nocturnal dyspnea
- Worsening edema
- Elevated BNP
- Re-evaluation
  - Known HF (systolic or diastolic)
    - With a change in clinical status or cardiac exam (as listed above)
    - Asymptomatic patient with change in GDMT

## Cardiomyopathy

- Initial evaluation of suspected inherited or acquired cardiomyopathy, including but not limited to: **(AUC 9)**<sup>(7)</sup>
  - Restrictive
  - Infiltrative/Depositional (i.e., hemochromatosis/iron overload, mucopolysaccharidoses, mitochondrial or metabolic storage disease (e.g., Danone disease, Fabry disease))
    - Fabry disease: annual surveillance TTE may be approved for patients receiving enzyme replacement<sup>(25)</sup>
  - Dilated
  - Hypertrophic
  - Re-evaluation of known cardiomyopathy if there is a need to monitor a change in medications or new symptoms, including but not limited to:
    - Chest pain
    - Shortness of breath
    - Palpitations
    - Syncope
- Heart failure (including Takotsubo cardiomyopathy)<sup>(25)</sup> with recovered left ventricular ejection fraction defined as (must meet all 3 criteria):
  - Documentation of a decreased LVEF <40% at baseline
  - ≥10% absolute improvement in LVEF
  - A second measurement of LVEF >40%<sup>(38)</sup>
    - Repeat echocardiogram every 6 months until 12-18 months after recovery of EF, then annually for 2 years, then every 3-5 years

- Higher risk patient (persistent left bundle branch block, genetic cardiomyopathy, higher biomarker profiles) may have annual follow-up
- Screening evaluation in first-degree relatives of a patient with an inherited cardiomyopathy **(AUC 9)**<sup>(7)</sup>
- Suspected cardiac sarcoidosis, including as a screening study in patients with biopsy proven extracardiac sarcoidosis<sup>(39)</sup>
- Suspected cardiac amyloid and to monitor disease progression and/or response to therapy, and to guide initiation and management of anticoagulation (TEE may be preferred)<sup>(40)</sup>
  - Light chain amyloidosis (AL): TTE may be repeated every 3-6 months
  - Transthyretin amyloidosis (ATTR): TTE may be repeated every 6-12 months<sup>(25)</sup>

## Hypertrophic Cardiomyopathy (HCM)<sup>(41)</sup>

- Initial evaluation of suspected HCM
- Re-evaluation of patients with HCM with a change in clinical status or a new clinical event
- Evaluation of the result of surgical myomectomy or alcohol septal ablation
- Re-evaluation in patients with no change in clinical status or events every 1 - 2 years to assess degree of myocardial hypertrophy, dynamic obstruction, MR, and myocardial function
- Evaluation of patients with HCM who have undergone septal reduction therapy within 3-6 months after the procedure
  - Screening for patients who are clinically unaffected or (genotype-positive and phenotype-negative):
    - Children and adolescents, every 1-2 years
    - Adults every 3-5 years
  - Screening of first-degree relatives is recommended at the time HCM is diagnosed in the family member and serial follow-up as below:
    - Children and adolescents from genotype-positive families and families with early onset disease every 1-2 years
    - All other children and adolescents every 2-3 years
    - Adults every 3-5 years
- To guide therapy
  - Camzyos (mevacamten): baseline TTE prior to initiation. Repeat TTE during therapy at the discretion of the ordering specialist.<sup>(42)</sup>

## Imaging Surveillance for Cardiotoxic Exposures <sup>(43,44)</sup>

- TTE is the method of choice for the evaluation of patients who will receive or have received cardiotoxic medication. TTE may be approved for:
  - Baseline assessment prior to initiation of therapy **(AUC 9)** <sup>(7)</sup>
  - Monitoring during therapy. The frequency of testing should be left to the discretion of the ordering physician, but in the absence of new abnormal findings, generally no more often than every 6 weeks while on active therapy. **(AUC 7)** <sup>(7)</sup>
  - Long term surveillance after completion of therapy may be required, especially for those who have been exposed to anthracycline medication. The frequency of testing is generally every 6-12 months, or at the discretion of the provider. **(AUC 7)** <sup>(7)</sup>

## Imaging Surveillance for Previous Radiation Therapy with Cardiac Exposure <sup>(45)</sup>

- TTE is indicated for long term surveillance, generally at 5 years and at 10 years following radiation exposure. More frequent surveillance may be indicated at the discretion of the provider.

## Device Candidacy or Optimization (Pacemaker, ICD, or CRT)

- Initial evaluation or re-evaluation after revascularization ( $\geq 90$  days) and/or myocardial infarction ( $\geq 40$  days) and/or 3 months of guideline-directed medical therapy when ICD is planned <sup>(46)</sup> **(AUC 9)** <sup>(7)</sup>
- Initial evaluation for CRT device optimization after implantation **(AUC 7)** <sup>(7)</sup>
- Re-evaluation for CRT device optimization in a patient with worsening heart failure **(AUC 8)** <sup>(7)</sup>
- Known implanted pacing device with symptoms possibly due to device complication or suboptimal pacing device settings **(AUC 8)** <sup>(7)</sup>

## Ventricular Assist Devices (VADs) and Cardiac Transplantation <sup>(7,47)</sup>

- To determine candidacy for VAD **(AUC 9)** <sup>(7)</sup>
- Optimization of VAD settings and assessment of response post device **(AUC 8)** <sup>(7)</sup>

- Re-evaluation for signs/symptoms suggestive of VAD-related complications, including but not limited to: **(AUC 8)**<sup>(7)</sup>
  - TIA or stroke
  - Infection
  - Murmur suggestive of aortic insufficiency
  - Worsening heart failure

## Post Heart Failure Transplant Surveillance Imaging

- Monitoring at the discretion of the transplant center for rejection in a cardiac transplant recipient. <sup>(48)</sup> **(AUC 8)**<sup>(7)</sup>

## Cardiovascular Disease in Pregnancy <sup>(9,49)</sup>

- Valvular stenosis
  - Mild can be evaluated each trimester and prior to delivery
  - Moderate-severe can be evaluated monthly
- Valvular regurgitation
  - Mild-moderate regurgitation can be evaluated each trimester and prior to delivery
  - Severe regurgitation can be evaluated monthly
- Pre-pregnancy evaluation with mechanical or bioprosthetic heart valves (if not done within the previous year) **(AUC 9)**<sup>(8)</sup>
- Peripartum Cardiomyopathy: can be repeated at the end of the 1st and 2nd trimesters, 1 month prior to delivery, 1 month postpartum, and serially including up to 6 months after normalization of ejection fraction
- Aortopathic syndromes (i.e., Marfan's, Ehlers-Danlos, Loeys-Dietz Syndrome, or Turner's Syndrome) or known dilated aortic root or ascending aorta: may be approved for pre-pregnancy planning and for monitoring each trimester during pregnancy and again several weeks post-partum. More frequent imaging may be approved depending on aortic diameter, aortic growth rate and comorbidities predisposing to dissection (i.e., presence of an aortopathic syndrome, HTN). <sup>(28)</sup>

## Adult Congenital Heart Disease <sup>(22,50)</sup>

- Initial evaluation including history, physical examination, electrocardiogram (ECG), or other imaging modality suggest adult congenital heart disease
- Screening of first-degree relatives of patients with a bicuspid aortic valve **(AUC 8)**<sup>(8)</sup>



- Known adult congenital heart disease with a change in clinical status or cardiac exam, including but not limited to:
  - Chest Pain
  - Shortness of breath
  - New or increased murmur on physical exam
- Evaluation prior to surgical or transcatheter procedure
- For follow-up of specific lesions, see **Table 1** and **Table 2** for Adult and Pediatric Congenital Heart Disease Follow-up

## Inflammatory and Autoimmune

- Including any one of the following:
  - Suspected rheumatic fever<sup>(51)</sup>
  - Systemic lupus erythematosus<sup>(52)</sup>
  - Takayasu arteritis<sup>(53)</sup>
  - Multisystem Inflammatory Syndrome in children (MIS-C): at baseline and for surveillance when there is documented concern for coronary involvement or other late sequelae<sup>(54)</sup>
  - Kawasaki disease<sup>(55)</sup>
    - Upon diagnosis, 1-2 weeks later, and 4 to 6 weeks after diagnosis
    - For patients with important and evolving coronary artery abnormalities during the acute illness, echocardiograms may need to be more frequent. In the setting of increasing size of coronary aneurysms, echocardiogram can be performed up to twice per week until dimensions have stopped progressing, then at least once per week in the first 45 days of illness, and then monthly until the third month after onset.
    - For persistent coronary aneurysm after the acute illness, echocardiogram surveillance intervals are based on the size of the aneurysm:
      - Small: at 6 months. and then yearly
      - Medium: at 3, 6 and 12 months and then every 6-12 months
      - Large/Giant: at 3, 6, 9 and 12 months and then every 3-6 months

## COVID-19<sup>(56)</sup>

- Acute infection
  - Cardiopulmonary signs or symptoms (ECG abnormalities, elevated biomarkers, chest pain, dyspnea, syncope, palpitations)

- Post-Acute Sequelae (PASC) defined as new or returning cardiopulmonary symptoms 4 or more weeks and persisting more than 2 months following confirmed COVID infection, not explained by an alternative diagnosis (World Health Organization definition).
- Post Vaccination
  - Symptoms or signs of myocarditis (ECG abnormalities, chest pain, elevated biomarkers)

## **Surveillance for Neuromuscular Disorders <sup>(57)</sup>**

Asymptomatic surveillance intervals (genetically affected individuals with no signs or symptoms of cardiac involvement). Development of signs or symptoms of cardiac involvement necessitates more frequent assessment.

- Duchenne muscular dystrophy (DMD) and Becker muscular dystrophy (BMD)
  - age <10 years, TTE every 2 years
  - age 10 years or older, TTE annually
- Emery-Dreifuss muscular dystrophy (EDMD)
  - X-linked form: at least annual TTE
  - Autosomal form: TTE at initial diagnosis, surveillance TTE only if initial TTE abnormal
- Myofibrillar myopathy (MFM)
  - Annual TTE
- Barth (BTHS)-X linked recessive (only males develop disease)
  - Infant males TTE every 6 months
  - Age 1 year or older, annual TTE
- Limb-Girdle muscular dystrophy (LGMD)
  - TTE may be performed annually
- Friedrich's ataxia (FA)
  - TTE can be performed at least annually
- Myotonic dystrophy (DM)
  - TTE every 2-4 years

## INDICATIONS FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE) PEDIATRIC PATIENTS (PATIENTS UNDER THE AGE OF 18) <sup>(34)</sup>

- Hypertension (see section: **Hypertension (Pediatric)**) (AUC 9) <sup>(34)</sup>
  - Initial evaluation (one time only)
  - Persistent hypertension despite two or more medications can be performed annually <sup>(33)</sup>
- Initial evaluation of Renal failure (AUC 7) <sup>(34)</sup>
- Palpitations, if one:
  - Family history at age < 50 of either: (AUC 7) <sup>(34)</sup>
    - Sudden cardiac death/arrest **OR**
    - Pacemaker or ICD
  - History or family history of cardiomyopathy (AUC 9) <sup>(34)</sup>
- Chest pain, if one or more of the following:
  - Exertional chest pain (AUC 8) <sup>(34)</sup>
  - Abnormal ECG (AUC 7) <sup>(34)</sup>
  - Family history with unexplained sudden death or cardiomyopathy (AUC 8) <sup>(34)</sup>
- Syncope, if any of the following:
  - Abnormal ECG (AUC 7) <sup>(34)</sup>
  - Exertional syncope (AUC 9) <sup>(34)</sup>
  - Family history at age < 50 of either one: (AUC 9) <sup>(34)</sup>
    - Sudden cardiac death/arrest **OR**
    - Pacemaker or ICD
  - Family history of cardiomyopathy
- Signs and/or symptoms of heart failure, including, but not limited to: (AUC 9) <sup>(34)</sup>
  - Respiratory distress
  - Poor peripheral pulses
  - Feeding difficulty
  - Decreased urine output
  - Edema
  - Hepatomegaly
- Abnormal physical findings, including any one of the following:

- Clicks, snaps, or gallops
- Fixed and/or abnormally split S2
- Decreased pulses
- Central cyanosis **(AUC 8)** <sup>(34)</sup>
- Arrhythmia, if one of the following:
  - Supraventricular tachycardia **(AUC 7)** <sup>(34)</sup>
  - Ventricular tachycardia **(AUC 9)** <sup>(34)</sup>
- Murmur
  - Pathologic sounding or harsh murmur, diastolic murmur, holosystolic or continuous murmur, late systolic murmur, grade 3/6 systolic murmur or louder, or murmurs that are provoked and become louder with changes in position **(AUC 9)** <sup>(34)</sup>
  - Presumptively innocent murmur, but in the presence of signs, symptoms, or findings of cardiovascular disease **(AUC 7)** <sup>(34)</sup>
- Abnormal basic data, including any one of the following:
  - Abnormal ECG **(AUC 7)** <sup>(34)</sup>
  - Abnormal cardiac biomarkers **(AUC 9)** <sup>(34)</sup>
  - Desaturation on pulse oximetry **(AUC 9)** <sup>(34)</sup>
  - Abnormal chest x-ray **(AUC 9)** <sup>(34)</sup>
- Sickle cell **(AUC 8)** <sup>(34)</sup>
  - One time screening for risk stratification for pulmonary hypertension in children ≥ 8 years of age <sup>(58)</sup>
- Suspicion of Structural Disease, including any one of the following:
  - Premature birth where there is suspicion of a Patent Ductus Arteriosus
  - Vascular Ring, based upon either one:
    - Difficulty breathing with stridor and eating solid foods that might suggest a vascular ring
    - Abnormal barium swallow or bronchoscopy suggesting a vascular ring **(AUC 7)** <sup>(34)</sup>
- Genetic & Syndrome Related, including any one of the following: **(AUC 7)** <sup>(34)</sup>
  - Genotype positive for cardiomyopathy, family history of hypertrophic cardiomyopathy or heritable pulmonary arterial hypertension
  - Patient with a known syndrome associated with congenital or acquired heart disease (Down's syndrome, Noonan's syndrome, DiGeorge syndrome, William's syndrome, Trisomy Thirteen, Trisomy Eighteen, Alagille syndrome, chromosomal abnormality associated with cardiovascular disease)

- Abnormalities of visceral or cardiac situs
- Known or suspected connective tissue diseases that are associated with congenital or acquired heart disease. (e.g., Marfan's, Loeys-Dietz)
- Patients with a first-degree relative with a genetic abnormality, such as cardiomyopathies (hypertrophic, dilated, arrhythmogenic right ventricular dysplasia, restrictive, left ventricular noncompaction).
- Maternal-Fetal related, including any one of the following:
  - Maternal infection during pregnancy or delivery with potential fetal/neonatal cardiac sequelae **(AUC 7)** <sup>(34)</sup>
  - Maternal phenylketonuria **(AUC 7)** <sup>(34)</sup>
  - Suspected cardiovascular abnormality on fetal echocardiogram **(AUC 9)** <sup>(34)</sup>

## CONGENITAL HEART DISEASE FOLLOW-UP<sup>‡</sup>\* (22)

### Adult and Pediatric

**[<sup>‡</sup>All surgical or catheter-based repairs allow evaluation PRIOR to the procedure and POSTPROCEDURAL evaluation (within 30 days)]**

- For all lesions, TTE is indicated for change in clinical status and/or development of new signs or symptoms
- Infant with any degree of unrepaired valvular AS/AR may have surveillance TTE every 1 – 4 weeks as needed
- Surveillance interval for patients with subvalvular stenosis **plus** aortic regurgitation will be dictated by the magnitude of the more significant abnormality (e.g., mild stenosis with moderate regurgitation would have surveillance interval as though stenosis were also moderate).
- Infant with any degree of unrepaired MS may have surveillance TTE every 1 – 4 weeks as needed
- After any surgical or catheter-based repair, evaluation (3-12 months) for a patient with heart failure symptoms
- Annual surveillance in a child with normal prosthetic mitral valve function and no LV dysfunction
- Surveillance (3-12 months) in a child with prosthetic mitral valve and ventricular dysfunction and/or arrhythmia
- Annual surveillance for incomplete or palliative repair (including but not limited to Glenn shunt, Fontan procedure and RV-PA conduit)
- TTE may be unnecessary in a year when cardiac MRI is performed unless clinical indication warrants otherwise

[\*Note: See tables below for specific surveillance intervals.]

Infancy is defined as between birth and 2 years of age; childhood from 2-12 years of age; and adolescence from 12 to 21 years of age<sup>(59)</sup>

**Table 1: Unrepaired Lesion Follow-Up‡ (22)**

‡Blue shading indicates lifetime surveillance interval

Unrepaired Lesion	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
<b>Aortic Stenosis (AS) and/or aortic regurgitation (AR)</b> (See <a href="#">section above</a> for surveillance intervals for infants)			Child Asymptomatic ≥ moderate AS/AR	Child Asymptomatic mild AS/AR	
<b>Bicuspid aortic valve with ≤ mild AS/AR and no aortic dilation in a child</b>				For adolescent	<b>3 Years</b>
<b>Atrial septal defect</b>				<b>Moderate size (6-12mm)</b>	<b>Small size (3-6mm)</b>
<b>Double outlet right ventricular (DORV): with balanced systemic and pulmonary circulation</b>	Infant	Child			
<b>Mitral regurgitation (MR)</b>	Infant with ≥ moderate MR		Infant with mild MR. Child with ≥ moderate MR.		Child with mild MR (2-5 years)
<b>Mitral Stenosis (MS)</b> (See <a href="#">section above</a> for surveillance intervals for infants)		Child with ≥ moderate MS		Child with mild MS	

Unrepaired Lesion	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
<b>Congenitally corrected transposition of the Great Arteries (ccTGA)</b>		Infant	<b>Moderate or greater A-V valve regurgitation</b>	<b>&lt; Moderate A-V valve regurgitation</b>	
<b>Tricuspid regurgitation (TR)</b>		Infant with $\geq$ moderate TR	Child with $\geq$ moderate TR	Child with mild TR	
<b>Patent Ductus Arteriosus</b>		Infant		Child	<b>Adult</b>
<b>Pulmonary stenosis (PS)</b>		Infant		Child <b>Adult</b>	
<b>Coarctation</b>		Infant		Child <b>Adult</b>	
<b>Ventricular septal defect (VSD)</b>	Infant with $\geq$ moderate VSD			Child with non-muscular VSD	Child with small muscular VSD <b>Adult with any VSD</b>
<b>Anomalous coronary arteries</b>				<b>Moderate to large coronary fistula</b>	<b>Small coronary fistula or RCA arising from left coronary sinus (2-5 years)</b>
<b>Subvalvular AS</b> See <a href="#">section above</a> for information on surveillance intervals for stenosis <b>plus</b> regurgitation	Infant with any degree of stenosis		Child with $\geq$ moderate stenosis <b>Adult with <math>\geq</math> moderate stenosis</b>	Child with mild stenosis <b>Adult with mild stenosis</b>	
<b>Supravalvular AS</b>		Infant with any degree of stenosis	Child with $\geq$ moderate stenosis <b>Adult with <math>\geq</math> moderate stenosis</b>	Child with mild stenosis <b>Adult with mild stenosis</b>	<b>2-5 years</b> <b>Adult with <math>\geq</math> moderate stenosis</b>

Unrepaired Lesion	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
<b>Total anomalous pulmonary venous connection (TAPVC)</b>	Prior to planned repair or for change in clinical status and/or development of new signs and symptoms				

**Note:** Despite surgical or catheter-based procedures, most patients with congenital heart disease are left with disorders or **sequelae** that are known consequences of the reparative intervention. These disorders can include arrhythmias, valvular and myocardial dysfunction, and vascular and non-cardiovascular abnormalities. These sequelae can be categorized as mild, moderate, or severe. Use clinical judgement to assess the nature of the sequelae when adjudicating cases based on the follow-up criteria below.

**Table 2: Postprocedural Follow-Up‡ (22)**

‡Blue shading indicates lifetime surveillance interval

Post-procedure: Surgical or Catheter-Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
<b>Post-procedural treatment of AS or AR with repair or replacement</b>	Infant with $\geq$ moderate AS or AR or LV dysfunction	Infant with $\leq$ mild AS or AR and no LV dysfunction	Child with $\geq$ moderate AS or AR	Child with $\leq$ mild AS or AR	
<b>ASD device closure: no or mild sequelae</b>	Within 1 <sup>st</sup> year	Within 1 <sup>st</sup> year	At 1 year		<b>2-5 years</b>
<b>ASD surgical repair: no or mild sequelae</b>			Within 1 <sup>st</sup> year		<b>2-5 years</b>
<b>ASD: device closure or surgical repair with residual shunt, valvular or ventricular dysfunction, arrhythmias, or</b>		<b>3-12 months</b>			



Post-procedure: Surgical or Catheter- Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
pulmonary hypertension					
DORV: no or mild sequelae			Within 1 <sup>st</sup> year	1-2 Years	
DORV: valvular or ventricular dysfunction, outflow obstruction, arrhythmias, branch pulmonary artery stenosis, presence of RV-PA conduit		3-12 months			
Tricuspid valve surgery or catheter-based procedure: no or mild sequelae				1-2 years	
Tricuspid valve surgery or catheter-based procedure: valvular or ventricular dysfunction or arrhythmias			Child	Adult	
Pulmonary Stenosis: no or mild sequelae			Child with moderate or severe sequelae	Child with no or mild sequelae	Adult
Coarctation: no or mild sequelae		Within 1 <sup>st</sup> year		After 1 <sup>st</sup> year	
PDA: no or mild sequelae				Annually within 1 <sup>st</sup> two years	Five years after 1 <sup>st</sup> two years*
PDA: post-procedural left PA stenosis or aortic obstruction				1-2 years	
Tetralogy of Fallot (ToF): after transcatheter pulmonary valve	1 month	6 months		Annually	

Post-procedure: Surgical or Catheter- Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
replacement, with no or mild sequelae					
ToF: patient with conduit dysfunction valvular or ventricular dysfunction, pulmonary artery stenosis, or arrhythmias			6-12 months		
Congenitally corrected transposition on the Great Arteries (ccTGA): no or mild sequelae		Within 1 <sup>st</sup> year		1-2 years	
ccTGA: valvular or ventricular dysfunction, outflow obstruction, ventricular - PA conduit		3-12 months			
d-TGA: no or mild sequelae	Infant with moderate sequelae	Within 1 <sup>st</sup> year		1-2 years	
d-TGA: moderate or greater valvular or ventricular dysfunction, outflow obstruction, branch pulmonary artery stenosis or arrhythmias, presence of RV-PA conduit		3-12 months			
d-TGA: dilated neo-aortic root and increasing Z-Score or neo-aortic regurgitation				1-2 years	
Truncus Arteriosus (TA): no or mild sequelae	Within 1 <sup>st</sup> year		After 1 <sup>st</sup> year		
TA:		3-6 months			

Post-procedure: Surgical or Catheter- Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
moderate or greater truncal stenosis / regurgitation					
TA: residual VSD, RV-PA conduit, branch pulmonary artery obstruction		3-12 months			
VSD: no or mild sequelae or small residual shunt			Within 1 <sup>st</sup> year		2-3 years
VSD: significant residual shunt, valvular or ventricular dysfunction, arrhythmias, or pulmonary hypertension		3-12 months			
Anomalous coronary arteries	Within 1 <sup>st</sup> year	Infant with or without ventricular or valvular dysfunction  Child or adult with ventricular or valvular dysfunction		Annually	
Subvalvular AS See <a href="#">section above</a> for information on surveillance intervals plus regurgitation	Infant with $\geq$ moderate stenosis	Infant with $\leq$ mild stenosis		Child with $\leq$ mild stenosis and/or AR  Adult with $\leq$ mild stenosis and/or AR	
Subvalvular AS <i>continued</i>		3-12 months Child $\geq$ moderate stenosis  3-12 months Adult $\geq$ moderate stenosis			

Post-procedure: Surgical or Catheter- Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
Supravalvular AS			Patient with $\geq$ moderate stenosis		2-5 years Patient with $\leq$ mild stenosis
Total anomalous pulmonary venous connection		Infant with mild or no sequelae		Child with mild or no sequelae	Adult with mild or no sequelae

\*PDA lifetime surveillance applies only to device closure; PDA lifetime surveillance is not indicated for surgical closure.

## CODING AND STANDARDS

### Coding

#### CPT Codes

93303, 93304, 93306, 93307, 93308, +93320, +93321, +93325, +93356

### 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 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. <sup>(3)</sup>

**Appropriate Care - Median Score 7-9**

**May be Appropriate Care - Median Score 4-6**

**Rarely Appropriate Care - Median Score 1-3**

## Acronyms / Abbreviations

AS: Aortic stenosis  
AR: Aortic regurgitation  
ASD: Atrial septal defect  
BNP: B-type natriuretic peptide or brain natriuretic peptide  
CABG: Coronary artery bypass grafting surgery  
CAD: Coronary artery disease  
ccTGA: Congenitally corrected transposition of the Great Arteries  
CMR: Cardiovascular magnetic resonance  
CRT: Cardiac resynchronization therapy  
CT: Computed tomography  
CVA: Cerebrovascular accident  
DORV: Double outlet right ventricle  
d-TGA: D-Transposition of the Great Arteries  
ECG: Electrocardiogram  
EF: Ejection fraction  
HCM: Hypertrophic cardiomyopathy  
HTN: Hypertension  
HF: Heart failure  
ICD: Implantable cardioverter-defibrillator  
LAA: Left atrial appendage  
LV: Left ventricular/ventricle  
LVEF: Left ventricular ejection fraction  
LVH: Left ventricular hypertrophy  
MI: Myocardial infarction  
MR: Mitral regurgitation  
MS: Mitral stenosis  
PA: Pulmonary artery  
PAC: Premature atrial complex  
PDA: Patent ductus arteriosus  
PFO: Patent foramen ovale  
PMVR: Percutaneous Mitral Valve Repair  
PS: Pulmonary stenosis  
PVC: Premature ventricular contraction  
RV: Right ventricular/ventricle  
TA: Truncus arteriosus  
TAVR: Transcatheter aortic valve replacement  
TEE: Transesophageal echocardiogram  
TIA: Transient ischemic attack  
ToF: Tetralogy of Fallot  
TR: Tricuspid regurgitation  
TTE: Transthoracic echocardiogram  
VAD: Ventricular assist device  
VF: Ventricular fibrillation  
VSD: Ventricular septal defect  
VT: Ventricular tachycardia

## POLICY HISTORY

### Summary

Date	Summary
June 2024	<ul style="list-style-type: none"> <li>● Added AUC Scoring to Cardiac Guidelines from published Societies. When an AUC score was not published by a Society, we assigned an AUC score of 6 based upon AUC scoring standards – this has been explained in Clinical Reasoning</li> <li>● Pediatric hypertension: Re-evaluation of patients' w/o LVH on initial evaluation can have TTE annually is new along with the criteria (state 2 HTN, secondary HTN, and chronic stage 1 HTN)</li> <li>● Under Prosthetic Valves/Native Valve Repair, the first bullet, "yearly thereafter" was removed because each bullet below has its own "year(s)" surveillance</li> </ul>
April 2023	<ul style="list-style-type: none"> <li>● Expanded and clarified indications based upon ECG abnormalities</li> <li>● Clarified arrhythmias (premature atrial complexes (PAC)) which do not meet criteria for approval.</li> <li>● Expanded and clarified surveillance imaging criteria for thoracic aortic aneurysm in Turner's syndrome</li> <li>● Added Takotsubo cardiomyopathy to section on surveillance for cardiomyopathy with recovered left ventricular ejection fraction</li> <li>● Expanded indication for screening in suspected cardiac sarcoidosis</li> <li>● Expanded section on post heart transplant surveillance</li> <li>● Added screening in children with sickle cell disease</li> <li>● Expanded section on aortopathic syndromes, cardiovascular disease in pregnancy</li> <li>● Clarified syncope indications</li> <li>● Pulmonary hypertension: added section for annual screening in certain diseases, added indication for repeat following pulmonary embolism evaluate for chronic thromboembolic pulmonary hypertension</li> <li>● Cardiomyopathy: added examples of infiltrative processes, added intervals for repeat testing in different forms of amyloidosis</li> <li>● Added indication for surveillance following radiation therapy</li> <li>● Hypertrophic cardiomyopathy: added statement on imaging related to Camzyos therapy</li> <li>● Clarified surveillance related to exposure to cardiotoxic medication</li> <li>● Added section on COVID</li> </ul>

Date	Summary
	<ul style="list-style-type: none"> <li>● Added section on inflammatory and autoimmune diseases</li> <li>● Added section on neuromuscular disorders</li> <li>● Reorganized Pediatric section for clarity</li> <li>● Added sections on supravulvar and subvalvular AS and total anomalous pulmonary venous connection to congenital heart disease table</li> <li>● Added statement on clinical indications not addressed in this guideline</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### Committee

Reviewed / Approved by Evolent Specialty 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. 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.*

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# EVOLENT CLINICAL GUIDELINE 066 FOR TRANSESOPHAGEAL ECHOCARDIOGRAM

<b>Guideline or Policy Number:</b> Evolent_CG_066	<b><u>Applicable Codes</u></b>	
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<b>Original Date:</b> October 2009	<b>Last Revised Date:</b> March 2024	<b>Implementation Date:</b> January 2025

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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.*

### Purpose

Transesophageal echocardiography (TEE) enables cardiac ultrasound imaging from within the esophagus, which provides a window for enhanced quality images as well as additional views, beyond that acquired by standard transthoracic echocardiography (TTE).

### 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. <sup>(1,2,3,4,5)</sup>

## INDICATIONS FOR TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE)

### General Criteria <sup>(6,7,8,9,10)</sup>

- TEE may be performed after a nondiagnostic transthoracic echocardiogram (TTE) due to inadequate visualization of relevant structures, or if there is a high likelihood of a nondiagnostic TTE **(AUC 7)** <sup>(11)</sup>

## Aortic Pathology

- Suspected acute aortic pathology, such as aortic dissection <sup>(6,12)</sup>
- Dilated aortic sinuses or ascending aorta on TTE **(AUC 7)** <sup>(11)</sup>
- Evaluation of aortic sinuses, sinotubular junction, or ascending aorta in patients with bicuspid aortic valve when morphology cannot be assessed by TTE, and other imaging including CT or MRI (Magnetic Resonance Imaging) have not been done **(AUC 7)** <sup>(11)</sup>

## Valvular Disease <sup>(6,13)</sup>

- Discordance between clinical assessment and TTE assessment of the severity of mitral regurgitation (MR) **(AUC 9)** <sup>(6)</sup>
- Evaluation of mitral stenosis, when there is a discrepancy between clinical signs or symptoms, and TTE is inadequate
- Discordance between clinical assessment and TTE assessment of the severity of aortic regurgitation (AR) **(AUC 8)** <sup>(6)</sup>
- Evaluation of native or prosthetic valves with clinical signs or symptoms suggesting valve dysfunction, when TTE is inadequate **(AUC 8)** <sup>(6)</sup>
- Re-evaluation of known prosthetic valve dysfunction when it would change management or guide therapy, (and TTE is inadequate) **(AUC 7)** <sup>(6)</sup>

## Infective Endocarditis <sup>(6,14,15)</sup>

- Suspected infective endocarditis (IE) of native valve, prosthetic valve, or endocardial lead with positive blood culture or new murmur **(AUC 8)** <sup>(6)</sup>
- Moderate to high pretest probability of IE (i.e., staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device) when TTE is negative **(AUC 9)** <sup>(6)</sup>
- Re-evaluation of IE in a patient with a change in clinical status or cardiac examination (e.g., new murmur, embolism, persistent fever, heart failure (HF), abscess, or atrioventricular block) **(AUC 8)** <sup>(6)</sup>
- Re-evaluation of IE if the patient is at elevated risk for progression/complications or when the findings alter therapy, when TTE is inadequate

## Cardiac Mass or Source of Emboli

- Initial evaluation of patient to exclude cardiac origin of TIA or ischemic stroke **(AUC 7)** <sup>(6)</sup>



- Evaluation of cardiac mass, suspected tumor, or thrombus, when other cardiac imaging is inconclusive <sup>(6,15)</sup>
- Re-evaluation of prior TEE finding for interval change (e.g., resolution of thrombus after anticoagulation), when the findings would change therapy **(AUC 7)** <sup>(6)</sup>

## **Atrial Fibrillation/Flutter** <sup>(6)</sup>

- Evaluation for clinical decision-making regarding anticoagulation, cardioversion, and/or radiofrequency ablation

## **TAVR (Transcatheter Aortic Valve Replacement/Repair)** <sup>(6,16)</sup>

**(AUC Score 7)** <sup>(6)</sup>

- Pre-procedural assessment of annular size and shape, number of cusps, and degree of calcification, when computed tomography (CT) or CMR (Cardiovascular Magnetic Resonance) cannot be performed
- Post-procedural assessment of degree of aortic regurgitation (including valvular and paravalvular) with suspicion of valve dysfunction, if TTE is inadequate

## **Patent Foramen Ovale or Atrial Septal Defect** <sup>(6,17)</sup>

**(AUC Score 8)** <sup>(11)</sup>

- Evaluation for anatomy, potential cardiac source of emboli, and suitability for percutaneous device closure
- Evaluation post device closure with clinical concern for infection, malposition, embolization, or persistent shunt

## **Left Atrial Appendage Occlusion** <sup>(11)</sup>

- Evaluation of anatomy, potential cardiac source of emboli, and suitability for percutaneous occlusion device placement **(AUC 9)** <sup>(11)</sup>
- Surveillance at 45 days and 1 year or FDA (U.S. Food and Drug Administration) guidance/guidelines for follow-up to assess device stability and device leak, and exclude migration, displacement, or erosion <sup>(18,19)</sup> **(AUC 8)** <sup>(11)</sup>
  - Reassessment at 6 months if 45-day TEE shows incomplete closure of left atrial appendage <sup>(18,19)</sup>

## Percutaneous Mitral Valve Repair <sup>(6)</sup>

- Determination of patient eligibility for percutaneous mitral valve procedures **(AUC 9)** <sup>(6)</sup>
- Procedural evaluation for percutaneous mitral valve procedures may be performed in addition to CT imaging <sup>(20)</sup>
- To exclude the presence of intracardiac mass, thrombus, or vegetation prior to (within 3 days of) the procedure **(AUC 9)** <sup>(6)</sup>

## Hypertrophic Cardiomyopathy <sup>(21)</sup>

- When TTE is inconclusive in planning for myectomy, to exclude subaortic membrane or mitral regurgitation, or to assess need for septal ablation

## Adult Congenital Heart Disease <sup>(17,22)</sup>

- Imaging with provocative maneuvers (Valsalva, cough) to assess the presence of right-to-left cardiac shunt **(AUC 7)** <sup>(17)</sup>
- Evaluation prior to planned repair of the following lesions when TTE, CMR, or CT are not adequate:
  - Isolated secundum atrial septal defect **(AUC 7)** <sup>(17)</sup>
  - Sinus venosus defect and/or partial anomalous pulmonary venous connection **(AUC 7)** <sup>(17)</sup>
  - Congenital mitral stenosis or mitral regurgitation **(AUC 7)** <sup>(17)</sup>
  - Subvalvular aortic stenosis **(AUC 7)** <sup>(17)</sup>
  - Transposition of the Great Arteries **(AUC 8)** <sup>(17)</sup>
- Evaluation postoperative or post catheter-based repair due to change in clinical status and/or new concerning signs or symptoms when TTE, CMR, or CT are not adequate **(AUC 7)** <sup>(17)</sup>

## Ventricular Assist Devices <sup>(6,23)</sup>

- Preoperative evaluation of suitability for ventricular assist device (VAD)
- Re-evaluation of VAD-related complication or suspected infection **(AUC 7)** <sup>(11)</sup>

## CODING AND STANDARDS

### Coding

#### *CPT Codes*

93312, 93313, 93314, 93315, 93316, 93317, 93318, +93320, +93321, +93325

### 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 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. <sup>(4)</sup>

**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  
 CMR: Cardiac magnetic resonance  
 CT(A): Computed tomography (angiography)  
 HF: Heart failure  
 IE: Infective endocarditis  
 MR: Mitral regurgitation  
 MRI: Magnetic resonance imaging  
 TAVR: Transcatheter aortic valve replacement/repair  
 TEE: Transesophageal echocardiography  
 TIA: Transient ischemia attack  
 TTE: Transthoracic echocardiography  
 VAD: Ventricular assist device

## POLICY HISTORY

### Summary

Date	Summary
March 2024	<ul style="list-style-type: none"> <li>● Added AUC Scoring to Cardiac Guidelines from published Societies. When an AUC score was not published by a Society, we assigned an AUC score of 6 based upon AUC scoring standards – this has been explained in Clinical Reasoning</li> <li>● Approvable having a TEE during a TAVR with criteria for pre and post procedural assessment</li> </ul>
April 2023	<ul style="list-style-type: none"> <li>● Added statement on clinical indications not addressed in this guideline</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### Committee

Reviewed / Approved by Evolent Specialty 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. 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.*

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# EVOLENT CLINICAL GUIDELINE 026 FOR STRESS ECHOCARDIOGRAM

<b>Guideline or Policy Number:</b> Evolent_CG_026	<b><u>Applicable Codes</u></b>	
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<b>Original Date:</b> February 2010	<b>Last Revised Date:</b> July 2024	<b>Implementation Date:</b> January 2025

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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.*

### Purpose

This guideline is for stress imaging, specifically Stress Echocardiography (SE) with appropriate preference for suitable alternatives, such as an exercise treadmill exam without imaging, when more suitable, unless otherwise stated (refer to **Background section**).

### Special Note

See **Legislative Requirements** for specific mandates in Washington State.

### 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. <sup>(1,2,3,4,5)</sup>

## INDICATIONS FOR STRESS ECHOCARDIOGRAPHY (6,7,8)

### Suspected Coronary Artery Disease (CAD)

- **Symptomatic patients without known CAD. No imaging stress test within the last 12 months.** The terms "typical," "atypical," and "non-anginal symptoms" can still be observed in medical records (consult the **Diamond Forrester table** in the **Definitions** section). However, the ACC has simplified its terminology to "Less likely anginal symptoms" and "Likely anginal symptoms" (refer to **Definitions**) and utilized below.
  - Less-likely anginal symptoms (**AUC 4-6**)
    - When baseline EKG makes standard exercise test inaccurate (see **Definitions** section).
    - When a noncardiac explanation is provided for symptoms, no testing is required (**AUC 8**)
  - Likely Anginal Symptoms (typical angina)
    - < 50 years old with ≤ one risk factor if an ECG treadmill test cannot be done. \*\*AUC scores for this bullet point are identical for MPI, stress echo, and ETT (**AUC = 7**). Although the ACC guideline does not specify youth and gender, decisions should be guided by best medical judgment, considering factors such as safety and radiation exposure.
    - ≥ 50 years old (**AUC 8**)
  - Repeat testing in patient with new or worsening symptoms and negative result at least one year ago AND meets one of the criteria above
- **Asymptomatic patients without known CAD**
  - Previously unevaluated ECG evidence of possible myocardial ischemia including ischemic ST segment or T wave abnormalities (see **Background** section)
  - Previously unevaluated pathologic Q waves (see **Background** section)
  - Previously unevaluated complete left bundle branch block

### Abnormal Calcium Scores (8,9,10,11,12)

- STABLE SYMPTOMS with a prior Coronary Calcium Agatston Score of >100. No prior stress imaging done within the last 12 months<sup>(10)</sup>
- ASYMPTOMATIC high global CAD risk patient with a prior Coronary Calcium Agatston Score of >100. No prior stress imaging done within the last 12 months<sup>(10)</sup>
- Asymptomatic patient with Coronary Calcium Agatston Score > 400. No prior stress imaging done within the last 12 months

## Inconclusive CAD Evaluation and Obstructive CAD Remains a Concern

- Exercise stress ECG with low-risk Duke treadmill score  $\geq 5$ , but patient's current symptoms indicate an increasing likelihood of disease
- Exercise stress ECG with an intermediate Duke treadmill score
- A previously unevaluated ventricular wall motion abnormality demonstrated by another imaging modality and stress echo is being performed to determine if the patient has myocardial ischemia. <sup>(8,13)</sup> **(AUC Score 8)** <sup>(8)</sup>
- Intermediate coronary computed tomography angiography (CCTA) defined as:
  - 40 -70% lesion
- Coronary stenosis of unclear significance on previous coronary angiography not previously evaluated <sup>(8)</sup>

## Follow-Up of Patient's Post Coronary Revascularization (PCI or CABG) <sup>(14)</sup>

- **Asymptomatic follow-up stress imaging** at a minimum of 2 years post coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) (whichever is later) is appropriate for patients with: **(AUC = 6)**
  - **High risk:** diabetes with accelerated progression of CAD, CKD, PAD, prior brachytherapy, ISR, or SVG intervention.
  - A history of silent ischemia or
  - A history of a prior left main stent

OR

- For patients with high occupational risk, associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers and firefighters
- **New, recurrent, or worsening symptoms, treated medically or by revascularization** is an indication for stress imaging, if it will alter management for typical anginal symptoms or symptoms documented to be similar to those prior to revascularization if no imaging stress test within the last 12 months. **(AUC Score 8)** <sup>(10)</sup>

## Follow-Up of Known CAD

- **Routine follow-up of asymptomatic or stable symptoms** when last invasive or non-invasive assessment of coronary disease showed hemodynamically significant CAD (ischemia on stress test or  $FFR \leq 0.80$  or significant stenosis in a major vessel

( $\geq 50\%$  left main coronary artery or  $\geq 70\%$  LAD, LCX, RCA)), over two years ago without intervening coronary revascularization, is an appropriate indication for stress imaging

## Special Diagnostic Conditions Requiring Coronary Evaluation

- Prior acute coronary syndrome (with documentation in MD notes), within last 12 months, without a prior stress test or coronary angiography performed since that time
- Newly diagnosed systolic heart failure or diastolic heart failure, **with reasonable suspicion of cardiac ischemia (prior events, risk factors)**, unless invasive coronary angiography is immediately planned<sup>(10,14)</sup> **(AUC Score 8)**<sup>(8)</sup>
- Ventricular arrhythmias:  
**AUC Score = 7**<sup>(8)</sup>
  - Sustained ventricular tachycardia (VT)  $> 100$  bpm, ventricular fibrillation (VF), or exercise-induced VT, when invasive coronary arteriography has not been performed<sup>(15)</sup>
  - Non-sustained VT, multiple episodes, each  $\geq 3$  beats at  $\geq 100$  bpm, frequent PVCs (defined as greater than or equal to 30/hour on remote monitoring), when an exercise ECG cannot be performed<sup>(15)</sup>
- For intermediate and high-risk global patients who require initiation of Class IC antiarrhythmic drugs. It can be performed annually thereafter until discontinuation of drug use<sup>(16)</sup> **(AUC Score 7)**<sup>(8)</sup>
- Hemodynamic assessment of ischemia in one of the following documented conditions:
  - Anomalous coronary arteries in an asymptomatic individual without prior stress echocardiography;<sup>(17)</sup>
  - Myocardial bridging of a coronary artery<sup>(18)</sup>
- Coronary aneurysms in Kawasaki's disease<sup>(19)</sup>
- Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter<sup>(20)</sup>

## Chronic Vascular Disease

### **Evaluation with Inclusion of Doppler**<sup>(21,22,23,24)</sup>

- For the evaluation of aortic stenosis and flow (contractile) reserve in symptomatic patients with severe aortic stenosis by calculated valve area, low flow / low gradient, and ejection fraction  $< 50\%$  **(AUC Score 8)**<sup>(14)</sup>

- For evaluation of asymptomatic moderate or severe aortic stenosis (AS) for measurement of changes in valve hemodynamics **(AUC Score 8)** <sup>(14)</sup>
- Non-severe aortic regurgitation (AR) with symptoms: Assessment of functional capacity and to assess for other causes of symptoms <sup>(8,14)</sup> **(AUC Score 7)** <sup>(14)</sup>
- For evaluation of mitral stenosis (MS) if there is:
  - Exertional shortness of breath which suggests the amount of MS is worse than is seen on the resting echocardiogram **(AUC Score 8)** <sup>(14)</sup>
- For evaluation for mitral regurgitation (MR) if there is:
  - Exertional shortness of breath which suggests the amount of MR is worse than is seen on the resting echocardiogram, **(AUC Score 8)** <sup>(14)</sup> **OR**
  - The echocardiogram is not able to distinguish whether the MR is moderate or severe in a patient that is asymptomatic **(AUC Score 7)** <sup>(14)</sup>
- For symptomatic patients with HCM, who do not have resting or provokable outflow tract gradient  $\geq 50$  mm Hg on TTE, for detection and quantification of dynamic LVOT obstruction <sup>(25)</sup>
- For asymptomatic patients with HCM who do not have a resting or provokable outflow tract gradient  $\geq 50$  mm Hg on TTE (Class 2A)

## Diastolic Function

- For unexplained dyspnea and suspected heart failure with preserved LVEF <sup>(8)</sup> (HFpEF) with normal or equivocal diastolic function on resting images

## Prior To Elective Non-Cardiac Surgery <sup>(7,26,27,28)</sup>

- An intermediate or high-risk surgery with of one or more risk factors (see below), AND documentation of an inability to walk (or  $<4$  METs) **AND** there has not been an imaging stress test within 1 year <sup>(26,27,29)</sup> **(AUC Score 8)**
  - **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 Risks:**
    - **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

## Pre Organ-Transplant

- Planning for any organ or stem cell transplantation is an indication for preoperative stress imaging, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, at the discretion of the transplant service. <sup>(7,30)</sup>  
**(AUC Score 8)**

## Post Cardiac Transplantation

- Annually, post cardiac transplantation, in a patient not undergoing invasive coronary arteriography

# LEGISLATIVE REQUIREMENTS

## State of Washington <sup>(31)</sup>

### *Health Technology Clinical Committee 20211105A*

#### **Number and coverage topic:**

**20211105A** – Noninvasive Cardiac Imaging for Coronary Artery Disease

#### **HTCC coverage determination:**

Noninvasive cardiac imaging is a **covered benefit with conditions**.

#### **HTCC reimbursement determination:**

**Limitations of coverage:** The following noninvasive cardiac imaging technologies are **covered with conditions**:

- Stress echocardiography for:
  - Symptomatic adult patients ( $\geq 18$  years of age) at intermediate or high risk of Coronary Artery Disease (CAD), or
  - Adult patients with known CAD who have new or worsening symptoms.
- Single Positron Emission Tomography (SPECT) for:
  - Patients under the same conditions as stress echocardiography when stress echocardiography is not technically feasible or clinically appropriate.
- Positron Emission Tomography (PET) for:
  - Patients under the same conditions as SPECT, when SPECT is not technically feasible or clinically appropriate.

- Coronary Computed Tomographic Angiography (CCTA) for:
  - Symptomatic adult patients (≥18 years of age) at intermediate or high risk of CAD, or
  - Adult patients with known CAD who have new or worsening symptoms.
- CCTA with Fractional Flow Reserve (FFR) for:
  - Patients under the same conditions as CCTA, when further investigation of functional significance of stenoses is clinically indicated.

**Non-covered indicators:**

N/A

**Notes:**

- Out of scope/data not reviewed for this decision:
  - Asymptomatic individuals, follow up of prior abnormal cardiac imaging studies, myocardial viability, preoperative evaluation
  - Patients presenting for evaluation of cardiac pathologies other than CAD
- This determination supersedes the following previous determinations:
  - Coronary Computed Tomographic Angiography for detection of Coronary Artery Disease (20081114A)
  - Cardiac Nuclear Imaging (20130920A)

## CODING AND STANDARDS

### Coding

#### ***CPT Codes***

93350, 93351, +93320, +93321, +93325, +93352, +93356

### 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 type="checkbox"/>	Medicare Advantage

## BACKGROUND

Stress echocardiography is an exercise stress test which utilizes echocardiography to provide information on exercise tolerance, ischemic burden, and structural heart disease including valvular disease and provides analysis of left ventricular function.

Stress echocardiography (SE) refers to ultrasound imaging of the heart during exercise electrocardiography (ECG) testing, during which visualized wall motion abnormalities can provide evidence of potential significant coronary artery disease (CAD).

While drug-induced stress with dobutamine can be an alternative to exercise stress testing in patients who are unable to exercise, this guideline does not require use of this modality. Hence, reference in this document to SE predominantly refers to exercise stress echocardiography.

Although SE provides comparable accuracy without radiation risk, relative to myocardial perfusion imaging (MPI), scenarios which do not permit effective use of SE might be better suited for stress imaging with MPI, cardiovascular magnetic resonance imaging (CMR) or positron emission tomography (PET), or coronary computed tomography angiography (CCTA).

Cardiac Doppler ultrasound is a form of ultrasound that can detect and measure blood flow. Doppler ultrasound depends on the Doppler Effect, a change in the frequency of a wave resulting from the motion of a reflector, the red blood cell. There are three types of Doppler ultrasound performed during a cardiac Doppler examination:

- Pulsed Doppler
- Continuous wave Doppler
- Color flow Doppler

## 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. <sup>(3)</sup>

**Appropriate Care - Median Score 7-9**

**May be Appropriate Care - Median Score 4-6**

**Rarely Appropriate Care - Median Score 1-3**

## Definitions

- Stable patients without known CAD fall into 2 categories: <sup>(6,7,8)</sup>
  - **Asymptomatic patients**, for whom Global Risk of CAD events can be determined from coronary risk factors using calculators available online (see **Websites for Global Cardiovascular Risk Calculators** section)



- **Symptomatic patients**, for whom we estimate the Pretest Probability that their chest-related symptoms are due to clinically significant CAD (see below):
- The medical record should provide enough detail to establish the type of chest pain:
  - **Likely Anginal symptoms** encompass chest/epigastric/shoulder/arm/jaw pain, chest pressure/discomfort occurring with exertion or emotional stress and relieved by rest, nitroglycerine or both.
  - **Less-Likely Anginal symptoms** include dyspnea, or fatigue not relieved by rest/nitroglycerin, as well as generalized fatigue or chest discomfort with a time course not indicative of angina (e.g., resolving spontaneously within seconds or lasting for an extended period unrelated to exertion).
- **Risk Factors for Coronary disease include (but not limited to):** diabetes mellitus, smoking, family history of premature CAD (men age less than 55, females less than 65), hypertension, dyslipidemia.
- Beginning 2023, the classification terms for angina were updated within the ACC's Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease to **Less Likely Anginal Symptoms** and **Likely Anginal Symptoms** as in #2. Previously, the document referred to "Typical Angina", "Atypical Angina" and "Non-Anginal" symptoms, defined by the **Diamond Forrester Table**. We still provide this information for your reference:<sup>(6,7,8)</sup>

### ***Diamond Forrester Table*** <sup>(32,33)</sup>

<b>Age (Years)</b>	<b>Gender</b>	<b>Typical/Definite Angina Pectoris</b>	<b>Atypical/Probable Angina Pectoris</b>	<b>Nonanginal Chest Pain</b>
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

- **Very low:** < 5% pretest probability of CAD, usually not requiring stress evaluation
- **Low:** 5 - 10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High:** > 90% pretest probability of CAD
- MPI may be performed without diversion to SE in any of the following:<sup>(8,34)</sup>
  - Inability to exercise
    - Physical limitations precluding ability to exercise for at least 3 full minutes of Bruce protocol

- Limited functional capacity (< 4 metabolic equivalents) **such as one** of the following:
      - Cannot take care of their activities of daily living (ADLs) or ambulate
      - Cannot walk 2 blocks on level ground
      - Cannot climb 1 flight of stairs
      - Cannot vacuum, dust, do dishes, sweep, or carry a small grocery bag
  - Other Comorbidities
    - Severe chronic obstructive pulmonary disease with pulmonary function test (PFT) documentation, severe shortness of breath on minimal exertion, or requirement of home oxygen during the day
    - Poorly controlled hypertension, with systolic BP > 180 or Diastolic BP > 120 (and clinical urgency not to delay MPI)
  - ECG and Echo-Related Baseline Findings
    - Prior cardiac surgery (coronary artery bypass graft or valvular)
    - Documented poor acoustic imaging window
    - Left ventricular ejection fraction ≤ 40%
    - Pacemaker or ICD
    - Persistent atrial fibrillation
    - Resting wall motion abnormalities that would make SE interpretation difficult
    - Complete LBBB
  - Risk-related scenarios
    - High pretest probability in suspected CAD
    - Intermediate or high global risk in patients requiring type IC antiarrhythmic drugs (prior to initiation of therapy and annually)
    - Arrhythmia risk with exercise
  - Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
    - 40 ms (1 mm) wide
    - 2 mm deep
    - 25% of depth of QRS complex
- ECG Stress Test Alone versus Stress Testing with Imaging
 

Prominent scenarios suitable for an ECG stress test **WITHOUT** imaging (i.e., exercise treadmill ECG test) are inferred from the guidelines presented above, often requiring that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate **AND** has an interpretable ECG for ischemia during exercise:<sup>(8)</sup>

- The (symptomatic) low or intermediate pretest probability patient who can exercise and has an interpretable ECG
- The patient who is under evaluation for exercise-induced arrhythmia
- For the evaluation of syncope or presyncope during exertion
- The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription

When exercise cannot be performed, pharmacologic stress can be considered.

- Duke Exercise ECG Treadmill Score <sup>(35)</sup>

Calculates risk from ECG treadmill alone:

- 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  $\leq -11$ ) categories.

- An uninterpretable baseline ECG includes:<sup>(6)</sup>

- ST segment depression is considered significant when there is 1 mm or more, not for non-specific ST- T wave changes
- Ischemic looking T waves are considered significant when there are at least 2.5 mm inversions (excluding V1 and V2)
- LVH with associated STT abnormalities, pre-excitation pattern such as WPW, a ventricular paced rhythm, or left bundle branch block
- Digitalis use
- Resting HR under 50 bpm on a medication, such as beta-blockers or calcium channel blockers, that is required for patient's treatment and cannot be stopped, with an anticipated suboptimal workload

- 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\* (36,37,38,39,40)**

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

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

- **Definitions of Coronary Artery Disease** (6,7,11,41,42)

Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).

- Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. Its incorporation into Global Risk can be achieved by using the MESA risk calculator.
- Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate), generally implies at least one of the following:
  - Suggested by percentage diameter stenosis  $\geq 70\%$  by angiography; intermediate lesions are 50 – 69% (8)
  - For a left main artery, suggested by a percentage stenosis  $\geq 50\%$  or minimum lumen cross-sectional area on IVUS  $\leq 6$  square mm (6,42,43)
  - FFR (fractional flow reserve)  $\leq 0.80$  for a major vessel (42,43)

- FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow
- Anginal Equivalent <sup>(6,44,45)</sup>  
Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia). This may include respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.

## Acronyms / Abbreviations

AAD: Antiarrhythmic drug  
ADLs: Activities of daily living  
BSA: Body surface area in square meters  
CABG: Coronary artery bypass grafting surgery  
CAC: Coronary artery calcium  
CAD: Coronary artery disease  
CCTA: Coronary computed tomography angiography  
CMR: Cardiovascular magnetic resonance imaging  
CT(A): Computed tomography (angiography)  
DTS: Duke Treadmill Score  
ECG: Electrocardiogram  
FFR: Fractional flow reserve  
HCM: Hypertrophic cardiomyopathy  
IVUS: Intravascular ultrasound  
LBBB: Left bundle-branch block  
LVEF: Left ventricular ejection fraction  
LVH: Left ventricular hypertrophy  
LVOT: Left ventricular outflow tract  
MESA: Multi-Ethnic Study of Atherosclerosis  
MET: Estimated metabolic equivalent of exercise  
MI: Myocardial infarction  
MPI: Myocardial perfusion imaging  
MR: Mitral regurgitation  
MS: Mitral stenosis  
PCI: Percutaneous coronary intervention  
PET: Positron emission tomography  
PFT: Pulmonary function test  
PVCs: Premature ventricular contractions  
SE: Stress echocardiography

TTE: Transthoracic echocardiography  
 VT: Ventricular tachycardia  
 VF: Ventricular fibrillation  
 WPW: Wolff-Parkinson-White

## POLICY HISTORY

### Summary

Date	Summary
July 2024	<ul style="list-style-type: none"> <li>● Added AUC Scoring to Cardiac Guidelines from published Societies. When an AUC score was not published by a Society, we assigned an AUC score of 6 based upon AUC scoring standards – this has been explained in Clinical Reasoning</li> <li>● Anginal symptoms have been changed to ‘less likely’ and ‘likely’ to coincide with the changed National Standards</li> <li>● Diamond Forrester Table has been taken out of the National Standards; however, it will remain in the guidelines as a historical information reference source</li> <li>● Added WA legislative requirement</li> </ul>
May 2023	<ul style="list-style-type: none"> <li>● Removed time limitation “within past two years” for further evaluation inconclusive prior CAD evaluation</li> <li>● Added coronary stenosis of unclear significance on coronary angiography</li> <li>● Added evaluation of asymptomatic moderate or severe aortic stenosis (AS) and aortic regurgitation (AR) for measurement of changes in valve hemodynamics</li> <li>● Added evaluation symptomatic patients with suspected diastolic dysfunction</li> <li>● Added statement on clinical indications not addressed in this guideline</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

**Reviewed / Approved by Evolent Specialty 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. 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.*

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# EVOLENT CLINICAL GUIDELINE 065 FOR HEART CATHETERIZATION

<b>Guideline or Policy Number:</b> Evolut_CG_065	<b><u>Applicable Codes</u></b>	
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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.*

### Purpose

Heart catheterization is an invasive angiographic procedure used to evaluate the presence and extent of coronary artery disease (CAD).

In addition to angiography, it can also include ventriculography, aortography, acquisition of hemodynamic data, measurement of cardiac output, detection and quantification of shunts and flows, intravascular ultrasound (IVUS), and fractional flow reserve (FFR)/instantaneous wave free ratio (iFR) for determination of a lesion's hemodynamic severity. CAD stenosis  $\geq 70\%$  ( $\geq 50\%$  in the left main coronary artery) is considered clinically significant or obstructive CAD. <sup>(1,2,3,4)</sup>

## 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.

In instances where an AUC has not been established through prior publication, 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. <sup>(5,6,7,8,9)</sup>

## INDICATIONS FOR INVASIVE CORONARY ARTERIOGRAPHY <sup>(1,10,11,12)</sup>

### General

- Typical angina with new onset or evolving ischemic EKG changes

- Prinzmetal's or variant angina (pain experienced at rest with ST elevation) on GDMT
- New onset or worsening of the patient's previously known anginal symptoms in a patient with a history of CABG or PCI (**AUC 7**)<sup>(4)</sup>
- Symptomatic patients with a high pretest probability (**AUC 7**)<sup>(4)</sup>
- Unheralded syncope (not near syncope), where the etiology is unclear
- Patient with CAD and symptoms of angina with intermediate or high-risk findings on non-invasive imaging stress test including stress induced LV dysfunction.

### ***Stable Ischemic Heart Disease***

- Exercise electrocardiogram (ECG) stress test with high-risk findings, such as Duke Score  $\leq -11$ , ST segment elevation, hypotension, exercise-induced ventricular tachycardia (VT), or greater than 1.0 mm persistent ST depression in multiple leads into recovery for 5 minutes or greater<sup>(11)</sup>
- Ischemia at low threshold on stress-testing with or without an abnormal decrease in normal systolic blood pressure response during exercise.
- Stress imaging with high-risk findings (see **Definitions**)
- Stress imaging with intermediate risk findings (see **Background** section) in a patient with one of the following:
  - Symptoms consistent with ischemia unresponsive to guideline directed medical therapy (GDMT)<sup>(11)</sup>
  - Unsatisfactory quality of life due to angina; interfering with the patient's occupation or the ability to perform usual activities<sup>(1)</sup>
  - Ejection fraction (EF)  $< 50\%$ <sup>(1)</sup>
- Non-invasive test with low-risk findings with new, worsening, or limiting symptoms with reasonable suspicion of cardiac origin despite optimal medical therapy (GDMT) or inability to tolerate GDMT<sup>(1,10,11)</sup>
- New, worsening, or limiting symptoms, with known unrevascularized obstructive coronary artery disease (CAD), in a patient eligible for revascularization<sup>(1,10)</sup>
- Post STEMI with "culprit only" revascularization and plan for further PCI of non-culprit lesion<sup>(13)</sup>
- Before high-risk non-cardiac surgery in patients who have evidence of ischemia by non-invasive testing.
- Discordant, equivocal, or inconclusive non-invasive evaluation in patients with suspected symptomatic stable ischemic heart disease, including the following:<sup>(3,4,11)</sup>
  - Low risk stress imaging with high-risk stress ECG response or stress induced typical angina<sup>(11)</sup>
  - Equivocal, uninterpretable, or inconclusive stress imaging due to issues of attenuation or other problems with interpretability<sup>(1,11)</sup>

## ***CCTA Abnormalities***

- Symptomatic patient with one of the following: <sup>(1,11,12)</sup>
  - One vessel with  $\geq 50\%$  stenosis (**AUC 7**) <sup>(4)</sup>
  - A stenosis of 40-90% and FFR-CT  $\leq 0.8$  <sup>(14)</sup> (**AUC 8**) <sup>(4)</sup>
  - $\geq 50\%$  left main stenosis, **even if asymptomatic**

## ***Heart Failure with Left Ventricular Dysfunction***

- New heart failure, cardiomyopathy, or wall motion abnormality in patients who are candidates for coronary revascularization, including one of the following <sup>(1,4,11,15)</sup> (**AUC 8**) <sup>(4)</sup>
  - Newly recognized heart failure in patients with known or suspected CAD
  - Symptomatic heart failure or ischemia with new, unexplained wall motion abnormality <sup>(1,11)</sup>
  - Structural abnormality (severe mitral regurgitation or ventricular septal defect) with reason to suspect ischemic origin
  - Deterioration in clinical status of heart failure or cardiomyopathy requiring invasive evaluation for guidance or alteration in therapy
  - Clarification of the diagnosis of myocarditis versus acute coronary syndrome <sup>(17)</sup>

## ***Ventricular Arrhythmias***

- Ventricular arrhythmias, without identified non-cardiac cause:
  - Following recovery from unexplained sudden cardiac arrest <sup>(18)</sup>
  - Sustained VT or VF (**AUC 7**) <sup>(4,11)</sup>
  - Exercise-induced VT (**AUC 7**) <sup>(4,11)</sup>

## ***Prior to Non-Coronary Intervention and Cardiac Surgery***

- Evaluation of coronary anatomy, with consideration of coronary revascularization, prior to cardiac surgery in patients with any of the following: <sup>(19,20,21,22)</sup>
  - Symptoms of angina
  - Stress imaging with evidence of ischemia
  - Decreased LV systolic function (EF < 50%)
  - History of CAD
  - Coronary risk factors, including men > 40 and postmenopausal women



- Non-invasive data that is inconclusive
- Severe valve disease
- Requirement for detailed assessment of coronary artery anatomy prior to aortic valve homograft surgery, pulmonary autograft (Ross procedure), or aortic root procedure
- Patients undergoing transcatheter aortic valve replacement (TAVR) or other transcatheter valve procedures
- Can be done pre-organ transplant when required by transplant center protocol in place of, but not in addition to an imaging study

### ***Hypertrophic Cardiomyopathy***

- Patients with HCM, who are candidates for SRT, and for whom there is uncertainty of LVOT obstruction on noninvasive imaging studies, invasive hemodynamic assessment with cardiac catheterization is recommended <sup>(23)</sup>
- In patients with symptoms or evidence of myocardial ischemia (CCTA also allowed)
- Prior to surgical myectomy in HCM patients who are at risk for coronary atherosclerosis (CCTA also allowed)

### ***Post Cardiac Transplantation***

Assessment for allograft vasculopathy annually <sup>(24)</sup>

### ***Hemodynamic Assessment***

- Indications for angiographic and/or hemodynamic assessment of valvular function or shunt physiology <sup>(11,19,25)</sup>
  - Assessment of bioprosthetic valve when transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) were inadequate, and cardiac magnetic resonance (CMR) or cardiac computed tomography (CCT) are not available
  - Assessment of mechanical valve prostheses when TTE and TEE are inadequate and CCTA is not available
  - Discordance between non-invasive data and clinical impression of severity of valvular disease
  - Evaluation of indeterminate shunt anatomy or shunt flows/ratio
- Indications for hemodynamic assessment only <sup>(11,25)</sup>
  - Assessment of constrictive and restrictive physiology

- Assessment of pulmonary hypertension when non-invasive data provides inadequate information for management, or to evaluate response to intravenous drug therapy
- Assessment of hemodynamics in heart failure, cardiomyopathy, or adult congenital heart disease, when
  - Non-invasive data is discordant or conflicts with the clinical presentation
  - Non-invasive data is inadequate for clinical management

## INDICATIONS FOR ASCENDING AORTOGRAPHY (19,21,22)

- Evaluation of aortic root dilatation in patients with severe aortic stenosis and regurgitation prior to valve surgery
- Evaluation of aortic root, ascending aortic aneurysm prior to repair
- Evaluation central shunts, Coarctation and great vessels
- Bypass graft identification at the time of left heart catheterization
- Disease affecting the aorta and coronary arteritis in which coronary artery involvement is suspected.

## CODING AND STANDARDS

### Coding

#### *CPT Codes*

93452, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, +93462, +93463, +93464, +93565, +93566, +93567, +93568

### Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

## BACKGROUND

Heart catheterization is the passage of a thin flexible tube (catheter) into the left or right heart systems via arteries or veins, respectively, for the purposes of hemodynamic measurements, acquisition of blood samples from specific locations, and/or the injection of radiopaque medium for the purposes of visualizing vascular anatomy. Coronary angiography is the passage of a catheter into the left side of the heart to diagnose or treat blockages of coronary arteries.

### **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. <sup>(5)</sup>

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

### **Definitions**

- Stable Patients without Known CAD fall into 2 categories: <sup>(1,3,4)</sup>
  - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Global Cardiovascular Risk Calculators section)
  - **Symptomatic**, for whom the pretest probability that chest-related symptoms are due to clinically significant CAD is estimated
- The Three Types of Chest Pain or Discomfort and Pretest Probability of CAD
  - **Typical Angina (Definite)** is defined as including all 3 characteristics:
    - Substernal chest pain or discomfort with characteristic quality and duration
    - Provoked by exertion or emotional stress
    - Relieved by rest and/or nitroglycerine
  - **Atypical Angina (Probable)** has only 2 of the above characteristics
  - **Non-anginal Chest Pain/Discomfort** has only 0 - 1 of the above characteristics
- The medical record should provide enough detail to establish the type of chest pain. From those details, the pretest probability of obstructive CAD is estimated from the Diamond Forrester Table below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability. <sup>(1,4)</sup>

**Diamond Forrester Table** <sup>(26,27)</sup>

Age (Years)	Gender	Typical/ Definite Angina Pectoris	Atypical/ Probable Angina Pectoris	Non-anginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

Low: 5 - 10% pretest probability of CAD

Intermediate: 10% - 90% pretest probability of CAD

High: > 90% pretest probability of CAD

- Coronary Risk Categories Derived from Non-invasive Testing <sup>(1,12)</sup>

- **High risk (> 3% annual death or MI)**

- Severe resting left ventricular (LV) dysfunction (LVEF < 35%) not readily explained by non-coronary causes
- Resting perfusion abnormalities ≥ 10% of the myocardium in patients without prior history or evidence of myocardial infarction (MI)
- Stress ECG findings including ≥ 2 mm of ST-segment depression at low workload or persisting into recovery, exercise-induced ST-segment elevation, or exercise-induced ventricular tachycardia (VT)/ventricular fibrillation (VF)
- Severe stress-induced left ventricular (LV) dysfunction (peak exercise EF < 45% or drop in EF with stress ≥ 10%)
- Stress-induced perfusion abnormalities involving ≥ 10% myocardium or stress segmental scores indicating multiple abnormal vascular territories
- Stress-induced LV dilation. Transient ischemic dilation (TID) is the ratio of left ventricular area immediately post-exercise divided by the area of the 4-hour redistribution image, with an abnormal ratio defined as > 1.12 <sup>(28)</sup>
- Inducible wall motion abnormality (involving ≥ 2 segments or ≥2 vascular territories)
- Wall motion abnormality developing at low dose of dobutamine (≤ 10 mg/kg/min) or at a low heart rate (< 120 beats/min)
- Multivessel obstructive CAD (≥ 70% stenosis) or left main stenosis (≥ 50% stenosis) on CCTA

- **Intermediate risk (1% to 3% annual death or MI)**

- Mild or moderate resting LV dysfunction (EF 35% to 49%) not readily explained by non-coronary causes

- Resting perfusion abnormalities in 5% to 9.9% of the myocardium in patients without a history or prior evidence of MI
- $\geq 1$  mm of ST-segment depression occurring with exertional symptoms
- Stress-induced perfusion abnormalities involving 5% to 9.9% of the myocardium or stress segmental scores (in multiple segments) indicating 1 vascular territory with abnormalities but without LV dilation
- Inducible wall motion abnormality involving 1 segment or 1 vascular territory
- CAC score 100 to 399 Agatston units (only for use in primary prevention, not for heart catheterization decision making) <sup>(1,3,11,29)</sup>
- One vessel CAD with  $\geq 70\%$  stenosis or moderate CAD stenosis (50% to 69% stenosis) in  $\geq 2$  arteries on CCTA
- **Low risk (< 1% annual death or MI)**
  - Low-risk treadmill score (score  $\geq 5$ ) or no new ST segment changes or exercise-induced chest pain symptoms, when achieving maximal levels of exercise
  - Normal or small myocardial perfusion defect at rest or with stress involving < 5% of the myocardium
  - Normal stress or no change of baseline wall motion abnormalities during stress
  - CAC score < 100 Agatston units (only for use in primary prevention, not for heart catheterization decision making) <sup>(1,3,11,29)</sup>
  - No coronary stenosis > 50% on CCTA
- 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.
    - **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%
  - **NOTE:** High global risk by itself generally lacks scientific support as an indication for stress imaging <sup>(30)</sup>. There are rare exemptions, such as patients

requiring I-C antiarrhythmic drugs, who might require coronary risk stratification prior to initiation of the drug, when global risk is moderate or high.

**Websites for Global Cardiovascular Risk Calculators\*** (29,31,32,33,34)

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

\*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

- Definitions of Coronary Artery Disease (1,3,12,35)
  - Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
  - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a risk stratification tool. Its incorporation into global risk can be achieved by using the MESA risk calculator.
  - Ischemia-producing disease (also called hemodynamically or functionally significant disease, or obstructive coronary disease for which revascularization might be appropriate) implies at least one of the following:
    - Suggested by percentage diameter stenosis  $\geq 70\%$  by angiography; intermediate lesions are 50 – 69% (11)
    - For a left main artery, suggested by a percentage stenosis  $\geq 50\%$  or minimum luminal cross-sectional area on IVUS  $\leq 6$  square mm (1,2,35)
    - FFR (fractional flow reserve)  $\leq 0.80$  for a major vessel (2,35)
    - iFR (instantaneous wave-free ratio)  $\leq 0.89$  for a major vessel (2,36,37,38)
  - A major vessel would be a coronary vessel that would be amenable to revascularization, if indicated. This assessment is made based on the

diameter of the vessel and/or the extent of myocardial territory served by the vessel.

- FFR is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow.
- Instantaneous wave-free ratio (iFR) measures the ratio of distal coronary to aortic pressure during the wave free period of diastole, with a value  $\leq 0.89$  considered hemodynamically significant. <sup>(36,37,38)</sup>
- Anginal Equivalent <sup>(1,39,40)</sup>
  - Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry, lung exam, etc. (as well as D-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.
- Optimal Medical Therapy (OMT)
  - In general, a trial of OMT includes
    - Anti-platelet therapy
    - Lipid-lowering therapy
    - Beta blocker
    - Angiotensin converting enzyme (ACE) inhibitor

## **Acronyms / Abbreviations**

CABG: Coronary artery bypass grafting surgery

CAC: Coronary artery calcium

CAD: Coronary artery disease

CCT: Cardiac computed tomography

CCTA: Coronary computed tomographic angiography

CMR: Cardiac magnetic resonance

CT(A): Computed tomography (angiography)

ECG: Electrocardiogram

EF: Ejection fraction

FFR: Fractional flow reserve

FFR-CT: Fractional flow reserve – computed tomography

HCM: Hypertrophic cardiomyopathy

iFR: Instantaneous wave-free ratio

IVUS: Intravascular ultrasound

LV: Left ventricular

LVEF: Left ventricular ejection fraction  
 LVOT: Left ventricular outflow tract  
 MESA: Multi-Ethnic Study of Atherosclerosis  
 MI: Myocardial infarction  
 MR: Mitral regurgitation  
 OMT: Optimal medical therapy  
 PCI: Percutaneous coronary intervention  
 PFT: Pulmonary function test  
 SRT: Septal reduction therapy  
 TAVR: Transcatheter aortic valve replacement  
 TID: Transient ischemic dilation  
 TTE: Transthoracic echocardiography  
 TEE: Transesophageal echocardiography  
 VT: Ventricular tachycardia  
 VF: Ventricular fibrillation

## POLICY HISTORY

### Summary

Date	Summary
February 2024	<ul style="list-style-type: none"> <li>● Formatting change</li> <li>● Addition of clinical reasoning statement with AUC scoring described</li> <li>● AUC scores added to bullet points</li> <li>● Indications for Ascending Aortography added</li> <li>● References updated</li> </ul>
April 2023	<ul style="list-style-type: none"> <li>● Added definition of unstable angina to include ischemic EKG changes</li> <li>● Added definition in background section on OMT (optimal medical therapy)</li> <li>● Added indication for revascularization of non-culprit lesion post STEMI</li> <li>● Added statement on clinical indications not addressed in this guideline</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### Committee

Reviewed / Approved by Evolent Specialty 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. 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.*

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