National Imaging Associates, Inc.*

2024 NIA Clinical Guidelines For Medical Necessity Review

EXPANDED CARDIAC GUIDELINES

Effective January 1, 2024 – December 31, 2024

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Guidelines for Clinical Review Determination

Preamble

NIA 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 National Imaging Associates, Inc. (NIA) 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. NIA'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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Clinical guidelines **FRACTIONAL FLOW RESERVE CT**	**Original Date: August 2017**
CPT Code: 75580	**Last Revised Date: April 2023**
Guideline Number: NIA_CG_062-1	**Implementation Date: January 2024**

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.*

INDICATIONS FOR FFR-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[1]
- Intermediate lesions in the above range and coronary calcification have made percentage stenosis interpretation difficult, thus could support approval of FFR-CT, in conjunction with the above criteria[2]

FFR-CT – ADDITIONAL INFORMATION[3,4]

None of the following clinical scenarios below apply, since FFR-CT either:

- Has not been adequately validated due to inapplicability of computational dynamics; **OR**
- Due to 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-CT is at the discretion of the vendor who provides the FFR-CT 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[5]

- 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
- Severe wall motion abnormality on CCTA results
- Severe myocardial hypertrophy
- High risk indicators on stress test
- Coronary angiography within the past 90 days
- Marginal quality of the submitted imaging data, due to motion, blooming, misalignment, arrhythmia, etc.

BACKGROUND[6,7]

Fractional flow reserve computed tomography (FFR-CT) is a relatively new technology that estimates the effect of coronary arterial narrowing on blood flow, based upon the images acquired in a coronary computed tomography angiography study. Its role is to provide information that can more appropriately select patients requiring invasive coronary angiography.

OVERVIEW

The Development of FFR-CT as a Technology

History of FFR: 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.[8-12]

Adaptation to CCTA: CCTA has shown utility in the evaluation of patients with stable chest pain, typically intermediate pretest probability, warranting non-invasive evaluation,[13-16] as well as in low-risk emergency department scenarios.[17] 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.[18]

FFR-CT Results: Quantitative estimation of coronary lesional hemodynamic severity using FFR-CT might enable deferral of invasive coronary arteriography when values are above 0.80, since such lesions would not warrant revascularization.

FFR-CT measurements appear reproducible,[19] with initial data demonstrating a strong correlation to invasive FFR, resulting in a high diagnostic performance.[20] Invasive FFR has excellent reproducibility[21] and a demonstrated track record of favorable outcomes when used in the selection of patients and vessels requiring PCI.[8,10-12] Evidence suggests that FFR-CT might be a better predictor of revascularization or adverse events than severe stenosis alone on CCTA[22] and that a negative FFR-CT in the evaluation of chest pain results in lower revascularization rates and lower cardiovascular death and MI at 1 year follow-up.[23] The FFR-CT data to date, however, provide no evidence showing that revascularization based upon FFR-CT improves clinical outcomes over invasive angiographic assessment. As a consequence of the above considerations, current revascularization guidelines do not advocate FFR-CT as a surrogate for invasive FFR, although, those guidelines refer to FFR-CT as an "emerging technology".[24]

Abbreviations

BMI	Body Mass Index
CCTA	Coronary Computerized Tomographic Angiography
FFR	Fractional Flow Reserve
FFR-CT	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

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POLICY HISTORY

Date	Summary
April 2023	• Added statement on clinical indications not addressed in this guideline • Deleted CPT codes 0501T, 0502T, 0503T, 0504T and replaced with 75580 to comply with AMA updates
March 2022	• Changed intermediate degrees of stenosis to 40 – 90% • Deleted Cardiac Implanted Electrical Devices and Prosthetic Heart Valves from list of clinical scenarios in which FFR-CT does not apply

Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guidelines **CARDIAC RESYNCHRONIZATION THERAPY (CRT)**	**Original Date: February 2013**
CPT Codes: 33221, 33224, 33225, 33231	**Last Revised Date: April 2023**
Guideline Number: NIA_CG_320	**Implementation Date: January 2024**

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. All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
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INDICATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY (CRT)[1-8]

Indications for CRT for patients are based upon 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). The beneficial effects of CRT have been extensively proven in patients with NYHA class II, III, and IV; there is limited evidence of CRT benefit in patients with NYHA functional class I. Other special situations, such as patients with atrial fibrillation or who require an upgrade from a conventional pacing or ICD system, will be addressed below as well.

Patients with cardiomyopathy on GDMT for 3 months or on GDMT and 40 days after MI; or with implantation of pacing or defibrillation device for special indications

CRT-D Indications by NYHA Heart Failure Class (see full definitions further below in document). See Background for Algorithm for CRT Indications/Recommendations in patients with cardiomyopathy or HFrEF chart.

- Class II- Ambulatory IV
  - LVEF ≤ 35%, QRS ≥ 120ms, LBBB, Sinus Rhythm
  - LVEF ≤ 35%, QRS ≥ 150ms, non-LBBB, Sinus Rhythm

Special Situations

- Independent/Regardless of NYHA Heart Failure Class
    - Patients who have 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
- Atrial fibrillation and LVEF ≤ 35% if:
    - Patient 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≤ 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
- In patients with nonobstructive HCM who have NYHA class II to IV heart failure with LBBB, LVEF < 50%, CRT therapy for symptom reduction is reasonable

NOT Indicated for Cardiac Resynchronization Therapy (CRT)

- NYHA class I and non-LBBB pattern with QRS duration < 150 ms,[3] except as in Special Situations section above
- Inotrope-dependent patients who have a higher risk need for cardiac transplant and LVAD support, are less likely to benefit from CRT
- Comorbidities and/or frailty expected to limit survival with good functional capacity to <1 year
- Active bloodstream infection
- Reversible causes are present such as toxic-, metabolic- or tachycardic-mediated cardiomyopathy, would require reassessment once the situation is corrected
- CRT has not been studied in ATTR-CM with HFrEF

Indications for CRT in Adult Congenital Heart Disease[9-11]

Systemic LV

- Systemic LV EF ≤ 35%, sinus rhythm, wide QRS complex ≥ 130 ms NYHA function Class II— IV

Any Systemic V

- Systemic ventricle any EF (not restricted to ≤ 35%), intrinsic narrow QRS complex, NYHA function Class I—IV and are undergoing new device placement or replacement with anticipated requirement for significant (>40%) ventricular pacing.

Any CHD

- CRT may be considered for patients with a severe subpulmonary RV dysfunction and dilatation despite interventions to decrease RV volume overload, NYHA function Class II—ambulatory IV and wide QRS complex ≥ 150 ms due to a complete RBBB
- NYHA function Class IV and severe ventricular dysfunction who would otherwise be candidates for heart transplantation or mechanical circulatory support

NOT Indicated for CRT in Adult Congenital Heart Disease

- Patients whose co-morbidities and/or frailty limit survival with good functional capacity to less than 1 year

INDICATIONS FOR CRT AS THE APPROPRIATE PACING MODALITY IN SPECIAL SITUATIONS WITH < 3 MONTHS OF GDMT[5, 12, 13]

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.

BACKGROUND[1, 3-5, 8]

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.[5]
- GDMT should have been in place continuously for at least 3 months[3, 4, 8] 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.
- The patient should have expected survival with reasonably good functional status for more than 1 year.[3, 4, 10]

OVERVIEW

NYHA Class Definitions[5, 14]

- 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[3]

- 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.

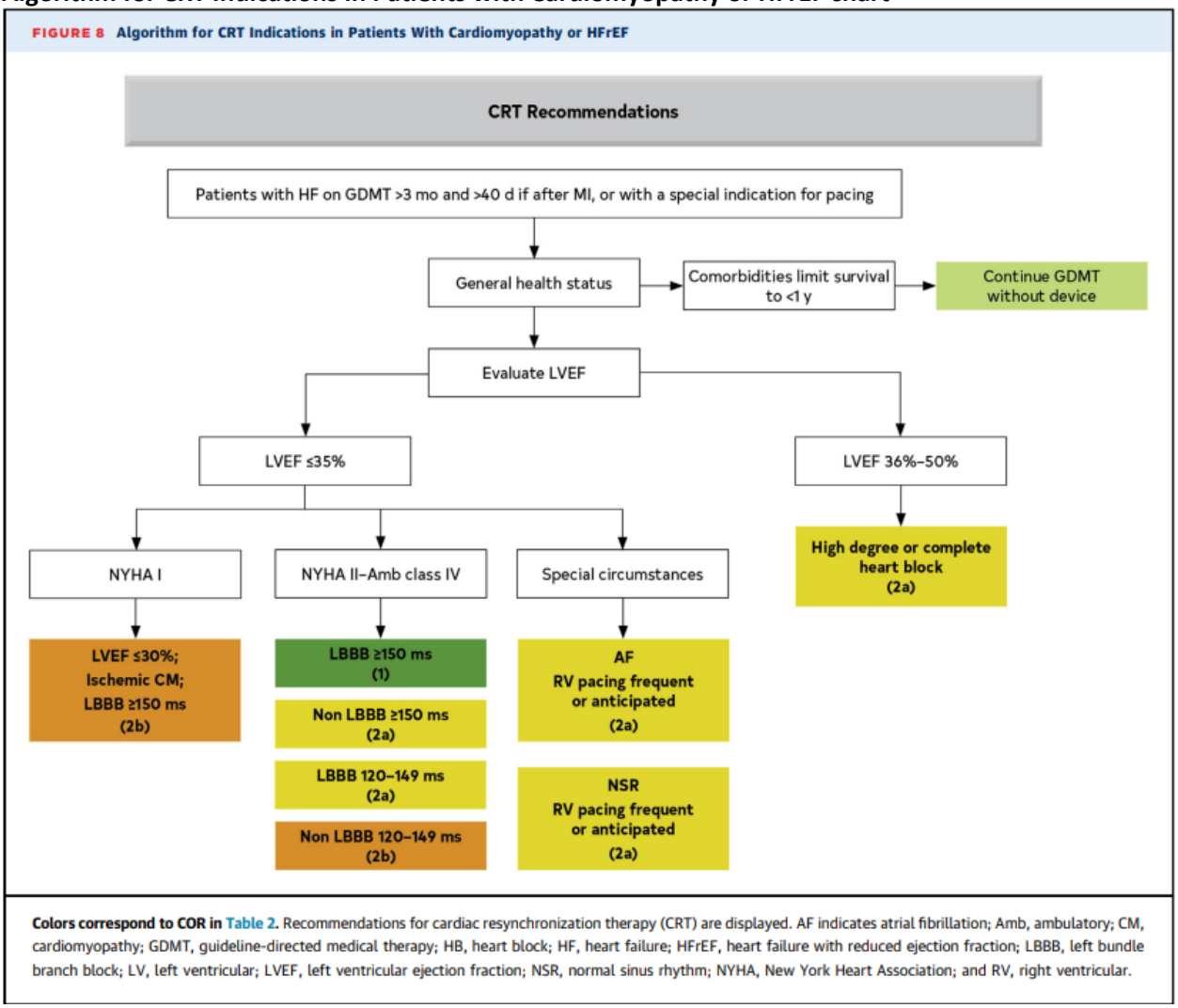
Guideline-Directed (or Optimal) Medical Therapy in Heart Failure[8]

- 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 ≥ 30 ml/min/1.73m2 and K+ < 5.0, NYHA class II-IV
- Not required for consideration of CRT: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm.

Algorithm for CRT Indications in Patients with Cardiomyopathy or HFrEF chart[15]



Colors correspond to COR in Table 2. Recommendations for cardiac resynchronization therapy (CRT) are displayed. AF indicates atrial fibrillation; Amb, ambulatory; CM, cardiomyopathy; GDMT, guideline-directed medical therapy; HB, heart block; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; LBBB, left bundle branch block; LV, left ventricular; LVEF, left ventricular ejection fraction; NSR, normal sinus rhythm; NYHA, New York Heart Association; and RV, right ventricular.

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

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POLICY HISTORY

Date	Summary
April 2023	• Added additional statement on atrial fibrillation • Added statement on ATTR • Added additional contraindication for patients with LVAD • Removed indication for Class I and CRT • Combined Class II- IV indications • Removed EF value for requirement for pacer • Added statement on clinical indications not addressed in this guideline
February 2022	• Added blood stream infection and reversibility as contraindication • Reworded NYHA • Removed single ventricle and RV

Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guideline **IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)**	**Original Date: February 2013**
CPT Codes: 33230, 33240, 33249	**Last Revised Date: April 2023**
Guideline Number: NIA_CG_321	**Implementation Date: January 2024**

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.*

All indications are predicated on a meaningful life expectancy of greater than one year if the ICD is implanted.

INDICATIONS FOR ICD INSERTION[1-7]

ISCHEMIC HEART DISEASE (CAD)[1, 4, 5]

Primary Prevention of SCD (prophylactic ICD implantation)

- LVEF ≤ 35% due to nonischemic or ischemic heart disease and NYHA class II or III, despite guideline-directed medical therapy (GDMT), and at least 40 days post-myocardial infarction (MI) who have reasonable expectation of meaningful survival of > 1 year
- LVEF ≤ 30% due to ischemic heart disease, NYHA class I, GDMT, and at least 40 days post-MI who have reasonable expectation of meaningful survival of > 1 year
- LVEF ≤ 40% with prior MI, NSVT, and inducible sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) at electrophysiological testing

Secondary Prevention of SCD

- Patients with documented ventricular fibrillation (VF), hemodynamically unstable ventricular tachycardia (VT), or sustained VT, after exclusion of reversible causes
- Syncope of undetermined origin, with inducible VF or sustained VT at electrophysiological study (EPS)
- Syncope of undetermined origin, with EF ≤ 35%

NONISCHEMIC CARDIOMYOPATHY (NICM)[1]

Primary Prevention of SCD (prophylactic ICD implantation)

- Lamin A/C gene mutation, with ≥ 2 risk factors from the following: NSVT, LVEF < 45%, male sex, missense mutation
- LVEF ≤ 35% and NYHA functional Class II or III, despite at least 3 months of GDMT: Recommended
- LVEF ≤ 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 ≤ 50% with unexplained syncope presumed to be due to VA and who do not meet indications for primary prevention ICD implantation

ADVANCED HEART FAILURE & TRANSPLANTATION[1, 5]

- In non-hospitalized patients with NYHA class IV who are candidates for cardiac transplantation or left ventricular assist device (LVAD)[1, 4, 5]
- In a patient with an LVAD, sustained ventricular arrhythmias[1]
- In NYHA ambulatory class IV, with appropriate indications for CRT (see Background Information section for definition of ambulatory NYHA class IV)

MYOCARDIAL DISEASES

Hypertrophic cardiomyopathy (HCM)

- Previously documented cardiac arrest or sustained ventricular tachycardia
- 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 ≤ 50 years of age
    - LVH ≥ 30 mm
    - At least 1 recent episode of syncope suspected by history to be arrhythmic (unlikely neurocardiogenic (vasovagal) and especially occurring within 6 months of evaluation (events beyond 5 years do not appear to have relevance))
    - LV apical aneurysm
    - LV systolic dysfunction (EF < 50%)

- Pediatric patients with HCM with at least 1 risk factor for SCD as follows:
    - Including unexplained syncope
    - LVH ≥ 30 mm
    - Nonsustained ventricular tachycardia
    - Family history of HCM-related SCD

NOTE: **ICD placement for the sole purpose of participation in competitive athletics should not be performed**

- **Cardiac Sarcoidosis** with one of the following[1, 3, 5]:
    - Cardiac arrest or documented sustained VT
    - LVEF ≤ 35%
    - LVEF > 35% with inducible sustained ventricular arrhythmia at EPS
    - Syncope and/or scar on CMR or positron emission tomography (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, Facioscapulohumeral)** with one of the following[1]:
    - Primary and secondary prevention, with same indications as for NICM[5]
    - Emery-Dreifuss or limb-girdle type I-B muscular dystrophy with progressive cardiac involvement
- **Arrhythmogenic right ventricular cardiomyopathy** and **at least 1** of the following risk factors for SCD[1-3, 8, 9]:
    - Resuscitated sudden cardiac arrest
    - Sustained VT
    - Right or left ventricular systolic dysfunction with an ejection fraction ≤ 35%
    - Syncope with documented or presumed ventricular arrhythmia

CHANNELOPATHIES

- **Congenital long QT syndrome** with **one** of the following[1, 2, 5, 10, 11]
    - Sudden cardiac arrest
    - Sustained VT or recurrent syncope when beta blocker is ineffective or not tolerated
    - QTc > 500 ms on a beta blocker[1]
    - Strong family history of SCD
    - High risk genotype
- **Brugada syndrome and spontaneous type 1 Brugada electrocardiographic pattern** with **one** of the following[1, 2, 5, 12]:
    - Cardiac arrest
    - Documented sustained ventricular arrhythmia
    - Syncope presumed to be due to ventricular arrhythmia
- **Catecholaminergic polymorphic VT** with **one** of the following[1, 2, 4, 13]:
    - 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[1, 5]:
    - Cardiac arrest
    - Sustained ventricular arrhythmia
- **Idiopathic Polymorphic VT/VF** with **one** of the following[1]:
    - Cardiac arrest due to polymorphic VT or VF

ADULT & PEDIATRIC CONGENITAL HEART DISEASE (CHD)[1, 3, 5, 14-16]

- Cardiac arrest due to VF or VT, or unstable VT, after exclusion of a reversible etiology
- Systemic LVEF ≤ 35%, biventricular physiology, and NYHA class II or III on GDMT
- Tetralogy of Fallot with one of the following[1, 3]:
    - Spontaneous sustained VT
    - Inducible VF or sustained VT
    - ≥ 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 ≥ 180 ms
        - Dilated right ventricle
        - Residual pulmonary regurgitation or stenosis
        - RV Hypertension
- Single or systemic right ventricular ejection fraction (RVEF) < 35%, in the presence of an additional risk factor such as:
    - NSVT
    - Unexplained syncope
    - NYHA class II or III, despite GDMT[1, 5]
    - QRS duration ≥ 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[1, 3]
- Syncope and moderate or severe complexity CHD, with high clinical suspicion of ventricular arrhythmias
- Non-hospitalized patients with CHD awaiting heart transplantation
- Left ventricular non-compaction that meets same indications as NICM, including a familial history of SCD[4, 17]

EXEMPTIONS

Indications for ICD with an Appropriate Pacing Modality in Special Situations[4, 18] *

- ICD criteria met, and elevated troponin is deemed not due to a myocardial infarction[1]
- 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[4] **
- 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[18]

*** 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

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

BACKGROUND[1-7]

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).

Patient eligibility for an ICD presumes all the following:

- Anticipated reasonable quality of life for ≥ 1-year post implantation[12]
- 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 ≥ 3 months of guideline-directed medical therapy (GDMT) for heart failure (HF), unless an intervening indication for pacemaker implantation arises (see Overview Information section for definition of GDMT)
- ICD indications are present in most scenarios in which cardiac resynchronization therapy (CRT) is appropriate
- Sustained VT is defined as having duration > 30 seconds or requiring termination due to hemodynamic compromise in < 30 seconds

Guidelines for the pediatric population are extrapolated from the adult population due to a lack of relevant trials.[5, 14]

OVERVIEW

General[1-7]

Implantable cardioverter defibrillators (ICDs) are indicated for the treatment of life-threatening ventricular tachycardia and ventricular fibrillation. 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).

- An ICD continually monitors heart rhythm. If a rapid rhythm is detected, the device delivers electrical therapy directly to the heart muscle to terminate the rapid rhythm and restore a normal heart rhythm. There are two types of therapy that can be delivered:
    - Rapid pacing OR
    - High-voltage shocks are necessary for ventricular fibrillation and when rapid pacing has failed to correct the abnormal rhythm
- In addition, all ICDs have pacing capability, and deliver pacing therapy for slow heart rhythms (bradycardia)
- The parameters defining limits for pacing therapy and for tachycardia therapy are programmable using noninvasive radio signals on all available ICDs

NYHA Class Definitions[4, 19, 20]

- **Class I:** No limitation of functional activity or only at levels of exertion that would limit normal individuals
- **Class II:** Slight limitation of activity. Fatigue, palpitation, or dyspnea with moderate exercise
- **Class III:** Marked limitation of activity. Fatigue, palpitation, or dyspnea with minimal activity
- **Class IV:** Severe limitation of activity. Symptoms even at rest, worse with activity
- **Ambulatory Class IV:** Class IV heart failure with 1) no active acute coronary syndrome; 2) no inotropes; and 3) on GDMT

Guideline-Directed (or Optimal) Medical Therapy for Heart Failure[7]

- Angiotensin converting enzyme (ACE-I), angiotensin receptor blockers (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
- Beta blockers
- Addition of loop diuretic for all NYHA class II – IV patients
- Addition of hydralazine and nitrate for persistently symptomatic African Americans
- Addition of an aldosterone antagonist, provided eGFR is > 30 ml/mi
- 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.

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

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POLICY HISTORY

Date	Summary
April 2023	• Added nonischemic CM indication for EF ≤ 35% and removed statement about requirement of 90-day post revascularization • Added statement on clinical indications not addressed in this guideline
February 2022	• Removed statement about hypertrophic cardiomyopathy being reasonable with family history of SCD

Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guidelines **PACEMAKER**	**Original Date: February 2013**
CPT Codes: **33206, 33207, 33208, 33212, 33213, 33214, 33227, 33228**	**Last Revised Date: April 2023**
Guideline Number: NIA_CG_322	**Implementation Date: January 2024**

GENERAL INFORMATION

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- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR PACEMAKERS – ADULT (Excludes conditions that are expected to resolve)[1, 2]

Sinus Node Dysfunction (SND)

- Documented symptomatic sinus bradycardia, including frequent sinus pauses
- Symptomatic chronotropic incompetence (broadly defined as an inability to increase heart rate commensurate with activity or demand), documented by stress test or cardiac monitoring data (Holter/MCOT/Electrocardiography (ECG)) recording data
- Symptomatic sinus bradycardia that results from required guideline-directed medical therapy (GDMT) for which there is no alternative treatment
- Heart rate less than 40 while awake, even without definite association with significant symptoms consistent with bradycardia
- Tachycardia-bradycardia syndrome and symptoms attributable to bradycardia[2]
- Syncope of unexplained origin with clinically significant SND, either documented or provoked in electrophysiologic study (EPS)

Acquired Atrioventricular (AV) Block

First-Degree AV Block

- Marked first-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block
- First-degree AV block with "pacemaker syndrome" symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise

Second-Degree AV Block (Mobitz Types I and II)

- Marked second-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block
- Second-degree AV block with "pacemaker syndrome" symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise
- Second-degree Mobitz Type II AV block regardless of symptoms
- Advanced second-degree AV block
- Second-degree AV block associated with a wide QRS, or EPS-documented intra- or infra-His conduction
- Symptomatic bradycardia associated with second-degree AV block, either Mobitz I or II

Third-Degree/Complete AV Block

- Third-degree (complete) AV block, intermittent or persistent, regardless of symptoms
- High-grade AV block, regardless of symptoms

AF/Other

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

Neuromuscular Disorders

- Marked first-degree or higher AV block, or an H-V interval ≥ 70 ms, associated with neuromuscular diseases, such as myotonic muscular dystrophy, Erb's dystrophy, Kearns-Sayre syndrome, and peroneal muscular atrophy, regardless of symptoms

Chronic Fascicular (Including any of RBBB, LBBB, LAHB, LPHB) Block

- Alternating bundle-branch block
- Syncope of unexplained origin when other likely causes have been excluded, specifically ventricular tachycardia[3]

- Syncope and bundle branch block with an HV interval ≥ 70 ms, or evidence of infranodal block at EPS[2]
- Incidental findings at EPS study of an H-V interval ≥ 100 milliseconds, or non-physiological, pacing-induced infra-His block in asymptomatic patients

Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

- Recurrent syncope due to spontaneously occurring carotid sinus stimulation AND carotid sinus pressure induced ventricular asystole ≥ 3 seconds, or AV block, or ≥ 50 mmHg drop in systolic BP[1, 3]
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole) ≥ 3 seconds
- Recurrent syncope and asystole ≥ 3 seconds with syncope or ≥ 6 seconds without symptoms or with presyncope, documented by ECG recording data[4, 5]

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
- Prevention of pause-dependent ventricular tachycardia (VT)

INDICATIONS FOR PEDIATRIC AND ADULT CONGENITAL HEART DISEASE PACING[1, 4, 6]

Children, Adolescents (< 19 years), and ADULT Patients with Congenital Heart Disease (CHD)

Sinus Node Dysfunction (SND)

- SND with symptomatic age- and activity-inappropriate bradycardia
- Sinus bradycardia with complex CHD AND a resting heart rate < 40 bpm **OR** pauses in ventricular rate > 3 seconds
- CHD and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony
- Asymptomatic sinus bradycardia following repair of CHD with an awake resting heart rate < 40 bpm or pauses in ventricular rate > 3 seconds
- CHD and SND or junctional bradycardia, for the prevention of recurrent episodes of intra-atrial reentrant tachycardia[4, 6, 7]

AV Block

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output
- Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction
- Congenital third-degree AV block in the infant with a ventricular rate < 55 bpm or with congenital heart disease and a ventricular rate < 70 bpm

- Congenital third-degree AV block after 1 year of age with an average heart rate < 50 bpm, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptoms due to chronotropic incompetence
- Adults with congenital complete AV block with symptomatic bradycardia, wide QRS escape rhythm, mean daytime heart rate < 50 bpm, complex ventricular ectopy, or ventricular dysfunction[2]
- Adults with congenital complete AV block, regardless of symptoms[2]
- 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

- 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

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BACKGROUND[1]

Pacemaker implantation generally serves to address bradycardia, with the intention of ameliorating related symptoms, preventing complications of syncope, and/or reducing mortality risk.

This guideline is not intended to cover the type of bradycardia pacing device. CRT (cardiac resynchronization therapy or biventricular pacing) and ICD (implantable cardioverter defibrillator) implantation are covered in separate guidelines.

OVERVIEW

General

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.

Leadless pacemakers are sometimes used as an alternative to transvenous pacemakers when no upper extremity venous access exists or when risk of device pocket infection is particularly high, such as previous infection and patients on hemodialysis.[8] Leadless pacemakers currently only have the capacity to pace the ventricle. The prevalence of leadless device infections is low as the principal source of infection.

Heart Block Definitions[1]

- 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

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

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POLICY HISTORY

Date	Summary
April 2023	• Additional statement on leadless pacemaker • Added statement on clinical indications not addressed in this guideline
February 2022	• Added section on leadless pacemakers

Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guideline **TRANSTHORACIC (TTE) ECHO**	**Original Date: October 2009**
CPT codes: 93303, 93304, 93306, 93307, 93308, +93320, +93321, +93325, +93356	**Last Revised Date: April 2023**
Guideline Number: NIA_CG_067	**Implementation Date: January 2024**

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.*

ADULT PATIENTS – INDICATIONS FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE)[1]

(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:
  - 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:
  - 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 (as documented in MD notes and on ECG).
    - New isolated RBBB is **not** an indication for TTE.
- Previously unevaluated left ventricular hypertrophy (i.e., concern for hypertrophic cardiomyopathy).

Murmur or Click

- Initial evaluation when there is a reasonable suspicion for valvular or structural heart disease such as:
    - High grade ≥ 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 ≥ 1 PVC on 12 lead ECG)
    - Isolated premature atrial complexes (PACs) are not an indication for TTE.
- Sustained or nonsustained ventricular tachycardia (VT) or ventricular fibrillation (VF), or ventricular bigeminy
- New onset atrial fibrillation (as documented in MD notes and on ECG) which was not evaluated by a prior transthoracic echocardiogram (TTE)

Syncope[2, 3]

- History, physical examination, or electrocardiogram (ECG) consistent with a cardiac diagnosis known to cause presyncope or syncope, including but not limited to, known or suspected:
    - 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[4, 5]

- Preoperative left ventricular function assessment in patients who are candidates for solid organ transplantation (can be done yearly prior to transplant)

Pulmonary Hypertension

- Evaluation of suspected pulmonary hypertension including evaluation of right ventricular function and estimated pulmonary artery pressure
- Re-evaluation of known pulmonary hypertension if there is a change in clinical status or cardiac exam or a need to change medications[6] such as:
    - 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[7]
    - Repeat TTE can be approved for persistent dyspnea 3-6 months after PE[8] to evaluate for possible chronic thromboembolic pulmonary hypertension (CTEPH)
- Annual screening can be performed for pulmonary hypertension in patients with[6, 9]:
    - Scleroderma
    - Portal hypertension (including evaluation prior to TIPS procedure)
    - Carriers of Bone Morphogenic Protein Receptor 2 (BMPR2) mutation
    - Sickle cell disease

Evaluation of Valvular Function[2, 10-12]

- Screening of first-degree relatives of patients with a bicuspid aortic valve

Native Valvular Stenosis

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

Native Valvular Regurgitation[2, 13, 14]

- Re-evaluation (≥ 3 yrs.) of mild valvular regurgitation
- Re-evaluation (≥ 1 yr) of moderate valvular regurgitation
- Re-evaluation of asymptomatic patient every 6 - 12 months with severe valvular regurgitation

Prosthetic Valves/Native Valve Repair

- Initial evaluation of prosthetic valve or native valve repair, for establishment of baseline, typically 6 weeks to 3 months postoperative

- Routine surveillance of surgical bioprosthetic valve: every 3 years after surgery
- Routine surveillance of surgical bioprosthetic and mechanical valve: at 10 years postoperatively and annually thereafter
- Routine surveillance of surgical mitral valve repair: 1-year post-op and then every 2-3 years
- Evaluation of prosthetic valve or native valve repair with suspected dysfunction, with symptoms including but not limited to:
    - 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)[2, 12, 15]

- Pre TAVR evaluation
- Post TAVR at 30 days (6 weeks to 3 months also acceptable) and annually
- Assessment post TAVR when there is suspicion of valvular dysfunction, including but not limited to:
    - Chest pain
    - Shortness of breath
    - New or increased murmur on heart examination
- Assessment of stroke post TAVR

Percutaneous Mitral Valve Repair[2, 12, 13]

- Pre-procedure evaluation
- Reassessment for degree of MR and left ventricular function (1, 6 months, and annually)

Closure of PFO or ASD[10]

- Pre-procedure evaluation
- Routine follow-up post procedure for device position and integrity (see Table 2: Adult and Pediatric Congenital Heart Disease Follow-Up)
- Evaluation for clinical concern for infection, malposition, embolization, or persistent shunt
- Routine surveillance of an asymptomatic patient with a PFO is **not** indicated[16]

Left Atrial Appendage (LAA) Occlusion[10]

- Pre-procedure evaluation

Pericardial Disease[7, 10, 17, 18]

- Suspected pericardial effusion
- Re-evaluation of known pericardial effusion when findings would lead to change in management
- Suspected pericardial constriction or reevaluation of status when management would be changed

Evaluation of Cardiac Source of Emboli or Cardiac Mass[2]

- Embolic source in patients with recent transient ischemic attack (TIA), stroke, or peripheral vascular emboli
- Evaluation of intracardiac mass or re-evaluation of known mass[19]

Infective Endocarditis (Native or Prosthetic Valves)[2, 11, 20]

- Initial evaluation of suspected infective endocarditis with positive blood cultures or a new murmur
- Re-evaluation of infective endocarditis with, but not limited to:
    - 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
- Re-evaluation of patient with infective endocarditis at high risk of progression or complication (extensive infective tissue/large vegetation, or staphylococcal, enterococcal, or fungal infections)
- At completion of antimicrobial therapy and serial examinations at 1, 3, 6, and 12 months during the subsequent year[20]

Thoracic Aortic Disease[21-26]

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 ≥ 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 2nd 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 ≥ 4.5 cm or showing growth rate ≥ 0.5 cm/year
- 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 ≥ 4.5 or expanding ≥ 0.5 cm/yr
- 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[27] (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.
- Evaluation of sinus of Valsalva aneurysms and associated shunting secondary to rupture.[25]

Hypertension (HTN) (Adult)[10,27]

- 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

Hypertension (HTN) (Pediatric)[28]

- 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 ≥140/90 mm Hg)
  - Secondary HTN
  - Chronic stage 1 HTN (BP between 130/80- and 139/89-mm Hg) incompletely treated, including drug resistance and noncompliance

Heart Failure[10, 29-31]

- Initial evaluation of suspected heart failure (HF) (systolic or diastolic) based on symptoms, signs, or abnormal test result, including but not limited to:
  - Dyspnea
  - Orthopnea
  - Paroxysmal nocturnal dyspnea
  - Worsening edema
  - Elevated BNP
- Re-evaluation of known HF (systolic or diastolic) with a change in clinical status or cardiac exam (as listed above)

Cardiomyopathy[10, 30-34]

- Initial evaluation of suspected inherited or acquired cardiomyopathy, including but not limited to:
  - 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[19]
  - 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)[19] 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%[35]:
        - 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
- Suspected cardiac sarcoidosis, including as a screening study in patients with biopsy proven extracardiac sarcoidosis[36]
- 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)[34]
    - Light chain amyloidosis (AL): TTE may be repeated every 3-6 months
    - Transthyretin amyloidosis (ATTR): TTE may be repeated every 6-12 months[19]

Hypertrophic Cardiomyopathy (HCM)[33]

- 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 physician[37].

Imaging Surveillance for Cardiotoxic Medication[38, 39]

- 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
    - 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.
    - 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.

Imaging Surveillance for Previous Radiation Therapy with Cardiac Exposure[40]

- 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 (≥ 90 days) and/or myocardial infarction (≥ 40 days) and/or 3 months of guideline-directed medical therapy when ICD is planned[41]
- Initial evaluation for CRT device optimization after implantation
- Re-evaluation for CRT device optimization in a patient with worsening heart failure
- Known implanted pacing device with symptoms possibly due to device complication or suboptimal pacing device settings

Ventricular Assist Devices (VADs) and Cardiac Transplantation[10, 42]

- To determine candidacy for VAD
- Optimization of VAD settings and assessment of response post device
- Re-evaluation for signs/symptoms suggestive of VAD-related complications, including but not limited to:
    - TIA or stroke
    - Infection
    - Murmur suggestive of aortic insufficiency
    - Worsening heart failure

Post Heart Transplant Surveillance Imaging

- Monitoring every 6 months (or at the discretion of the transplant center) for rejection in a cardiac transplant recipient. May be approved for more frequent monitoring in the first-year post-transplant[43].

Cardiovascular Disease in Pregnancy[32, 44]

- 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)
- Prior Postpartum Cardiomyopathy: can be repeated at the end of the 1st and 2nd trimesters, 1 month prior to delivery, after delivery prior to hospital discharge, 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, or Turner's) 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)[27].

Adult Congenital Heart Disease[16, 45, 46]

- Initial evaluation of suspected adult congenital heart disease
- 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**: Adult and Pediatric Congenital Heart Disease Follow-up**

Inflammatory & Autoimmune

- Including any one of the following:
  - Suspected rheumatic fever[47]
  - Systemic lupus erythematosus[48]

- Takayasu arteritis[49]
- Multisystem Inflammatory Syndrome (MIS): at baseline and for surveillance when there is documented concern for coronary involvement or other late sequelae[50]
- Kawasaki disease[51]
    - 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[52]

- 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 (WHO definition).
- Post Vaccination
    - Symptoms or signs of myocarditis (ECG abnormalities, chest pain, elevated biomarkers)

Surveillance for Neuromuscular Disorders[53]

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

PEDIATRIC PATIENTS - INDICATIONS FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE) (PATIENTS UNDER THE AGE OF 18)[54]

- Hypertension (see section: Hypertension (Pediatric))
- Renal failure
- Palpitations, if one:
    - Family history at age < 50 of either:
        - Sudden cardiac death/arrest **OR**
        - Pacemaker or ICD
    - History or family history of cardiomyopathy
- Chest pain, if one or more of the following:
    - Exertional chest pain
    - Abnormal ECG
    - Family history with unexplained sudden death or cardiomyopathy
- Syncope, if any of the following:
    - Abnormal ECG
    - Exertional syncope
    - Family history at age < 50 of either one:
        - Sudden cardiac death/arrest **OR**
        - Pacemaker or ICD
    - Family history of cardiomyopathy
- Signs and/or symptoms of heart failure, including, but not limited to:
    - 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
- Arrhythmia, if one of the following:
    - Supraventricular tachycardia
    - Ventricular tachycardia
- 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
    - Presumptively innocent murmur, but in the presence of signs, symptoms, or findings of cardiovascular disease
- Abnormal basic data, including any one of the following:
    - Abnormal ECG
    - Abnormal cardiac biomarkers
    - Desaturation on pulse oximetry
    - Abnormal chest x-ray
- Sickle cell
    - One time screening for risk stratification for pulmonary hypertension in children ≥ 8 years of age[55]
- 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
- Genetic & Syndrome Related, including any one of the following:
    - 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

- Maternal phenylketonuria
- Suspected cardiovascular abnormality on fetal echocardiogram

ADULT AND PEDIATRIC CONGENITAL HEART DISEASE FOLLOW-UP[16] ‡*
[‡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 1 year of age; childhood from 1-11 years of age; and adolescence from 11 to 21 years of age[56]

Table 1: Unrepaired Lesion Follow-Up‡
‡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
Aortic Stenosis (AS) and/or aortic			Child Asymptomatic ≥ moderate AS/AR	Child Asymptomatic mild AS/AR	

regurgitation (AR) (See section above for surveillance intervals for infants)					
Bicuspid aortic valve with ≤ mild AS/AR and no aortic dilation in a child					**3 Years**
Atrial septal defect				**Moderate size (6-12mm)**	**Small size (3-6mm)**
Double outlet right ventricular (DORV): with balanced systemic and pulmonary circulation	Infant	Child			
Mitral regurgitation (MR)	Infant with ≥ moderate MR		Infant with mild MR. Child with ≥ moderate MR.		Child with mild MR (2-5 years)
Mitral Stenosis (MS) (See section above for surveillance intervals for infants)		Child with ≥ moderate MS		Child with mild MS	
Congenitally corrected transposition of the Great Arteries (ccTGA)		Infant	**Moderate or greater A-V valve regurgitation**	**< Moderate A-V valve regurgitation**	
Tricuspid regurgitation (TR)		Infant with ≥ moderate TR	Child with ≥ moderate TR	Child with mild TR	
Unrepaired Lesion	**Surveillance Intervals**				
	1-3 months	**3-6 months**	**6-12 months**	**1-2 years**	**3-5 years**
Patent Ductus Arteriosus		Infant		Child	**Adult**
		Infant		Child	

Pulmonary stenosis (PS)				**Adult**	
Coarctation		Infant		Child **Adult**	
Ventricular septal defect (VSD)	Infant with ≥ moderate VSD			Child with non-muscular VSD	Child with small muscular VSD **Adult with any VSD**
Anomalous coronary arteries				**Moderate to large coronary fistula**	**Small coronary fistula or RCA arising from left coronary sinus (2-5 years)**
Subvalvular AS See section above for information on surveillance intervals for stenosis **plus** regurgitation	Infant with any degree of stenosis		Child with ≥ moderate stenosis **Adult with ≥ moderate stenosis**	Child with mild stenosis **Adult with mild stenosis**	
Supravalvular AS		Infant with any degree of stenosis	Child with ≥ moderate stenosis **Adult with ≥ moderate stenosis**	Child with mild stenosis **Adult with mild stenosis**	**2-5 years** **Adult with ≥ moderate stenosis**
Total anomalous pulmonary venous connection (TAPVC)	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‡
‡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
Post-procedural treatment of AS or AR with repair or replacement	Infant with ≥ moderate AS or AR or LV dysfunction	Infant with ≤ mild AS or AR and no LV dysfunction	Child with ≥ moderate AS or AR	Child with ≤ mild AS or AR	
ASD device closure: no or mild sequelae	Within 1st year	Within 1st year	At 1 year		**2-5 years**
ASD surgical repair: no or mild sequelae			Within 1st year		**2-5 years**
ASD: device closure or surgical repair with residual shunt, valvular or ventricular dysfunction, arrhythmias, or pulmonary hypertension		**3-12 months**			
DORV: no or mild sequelae			Within 1st year	**1-2 Years**	
DORV: valvular or ventricular dysfunction, outflow obstruction, arrythmias, branch pulmonary artery stenosis, presence of RV-PA conduit		**3-12 months**			

Post-procedure: Surgical or Catheter-Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
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 1st year		**After 1st year**	
PDA: no or mild sequelae				Annually within 1st two years	**Five years after 1st two years***
PDA: post-procedural left PA stenosis or aortic obstruction				**1-2 years**	
Tetralogy of Fallot (ToF): after transcatheter pulmonary valve replacement, with no or mild sequelae	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
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 1st 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 1st 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			

Post-Procedure: Surgical or Catheter-Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
d-TGA: dilated neoaortic root and increasing Z-Score or neoaortic regurgitation				1-2 years	
Truncus Arteriosus (TA): no or mild sequelae	Within 1st year		After 1st year		
TA: moderate or greater truncal stenosis / regurgitation		3-6 months			
TA: residual VSD, RV-PA conduit, branch pulmonary artery obstruction		3-12 months			
VSD: no or mild sequelae or small residual shunt			Within 1st year		2-3 years
VSD: significant residual shunt, valvular or ventricular dysfunction, arrhythmias, or pulmonary hypertension		3-12 months			

<table>
<tr><th rowspan="2">Post-procedure: Surgical or Catheter-Based</th><th colspan="5">Surveillance Intervals</th></tr>
<tr><th>1-3 months</th><th>3-6 months</th><th>6-12 months</th><th>1-2 years</th><th>3-5 years</th></tr>
<tr><td>Anomalous coronary arteries</td><td>Within 1st year</td><td>Infant with or without ventricular or valvular dysfunction

Child or adult with ventricular or valvular dysfunction</td><td></td><td>Annually</td><td></td></tr>
<tr><td>Subvalvular AS
See section above for information on surveillance intervals plus regurgitation</td><td>Infant with ≥ moderate stenosis</td><td>Infant with ≤ mild stenosis</td><td></td><td>Child with ≤ mild stenosis and/or AR
Adult with ≤ mild stenosis and/or AR</td><td></td></tr>
<tr><td>Subvalvular AS
continued</td><td></td><td colspan="2">3-12 months
Child ≥ moderate stenosis
3-12 months
Adult ≥ moderate stenosis</td><td></td><td></td></tr>
<tr><td>Supravalvular AS</td><td></td><td></td><td>Patient with ≥ moderate stenosis</td><td></td><td>2-5 years
Patient with ≤ mild stenosis</td></tr>
<tr><td>Total anomalous pulmonary venous connection</td><td></td><td>Infant with mild or no sequelae</td><td></td><td>Child with mild or no sequelae</td><td>Adult with mild or no sequelae</td></tr>
</table>

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

BACKGROUND

Transthoracic echocardiography (TTE) uses ultrasound to image the structures of the heart in a real time format, 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.

TTE's safety and versatility in examining cardiac structure, function, and hemodynamics lends to its utility for numerous indications in children and adults.

TEE (transesophageal echocardiography) widens the scope of utility for echocardiographic imaging, and its indications are covered in a separate guideline.

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
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

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POLICY HISTORY

Date	Summary
April 2023	• Expanded and clarified indications based upon ECG abnormalities • Clarified arrhythmias (premature atrial complexes (PAC)) which do not meet criteria for approval. • Expanded and clarified surveillance imaging criteria for thoracic aortic aneurysm in Turner's syndrome • Added Takotsubo cardiomyopathy to section on surveillance for cardiomyopathy with recovered left ventricular ejection fraction • Expanded indication for screening in suspected cardiac sarcoidosis • Expanded section on post heart transplant surveillance • Added screening in children with sickle cell disease • Expanded section on aortopathic syndromes, cardiovascular disease in pregnancy • Clarified syncope indications • Pulmonary hypertension: added section for annual screening in certain diseases, added indication for repeat following pulmonary embolism evaluate for chronic thromboembolic pulmonary hypertension • Cardiomyopathy: added examples of infiltrative processes, added intervals for repeat testing in different forms of amyloidosis • Added indication for surveillance following radiation therapy • Hypertrophic cardiomyopathy: added statement on imaging related to Camzyos therapy • Clarified surveillance related to exposure to cardiotoxic medication • Added section on COVID • Added section on inflammatory and autoimmune diseases • Added section on neuromuscular disorders • Reorganized Pediatric section for clarity • Added sections on supravalvular and subvalvular AS and total anomalous pulmonary venous connection to congenital heart disease table • Added statement on clinical indications not addressed in this guideline
June 2022	• Within the Hypertrophic Cardiomyopathy section, added To guide therapy
February 2022	• Modified definition of pathological Q waves • Added indications for murmur evaluation • Clarified definition of frequent PVC • Added annual surveillance TTE following palliative procedures in congenital heart disease.

	• Added post op atrial switch for d-TGA surveillance intervals (table) • Screening for PH in sickle cell added • Revised surveillance indications post op prosthetic valve and native valve repair • Expanded guidelines for AS/AR, MS/MR, TR, PS, ASD, TOF, DORV, TGA, TA, and coronary anomalies • Reorganized pediatric indications for clarity • Added section for pediatric hypertension (both initial evaluation and follow-up)

Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guideline **TRANSESOPHAGEAL (TEE) ECHO**	**Original Date: October 2009**
CPT codes: 93312, 93313, 93314, 93315, 93316, 93317, 93318, +93320, +93321, +93325	**Last Revised Date: April 2023**
Guideline Number: NIA_CG_066	**Implementation Date: January 2024**

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.*

INDICATIONS FOR TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE)

General Criteria[1-5]

- 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

Aortic Pathology

- Suspected acute aortic pathology, such as aortic dissection[1,6]
- Dilated aortic sinuses or ascending aorta on TTE
- 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

Valvular Disease[1,7]

- Discordance between clinical assessment and TTE assessment of the severity of mitral regurgitation (MR)

- 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)
- Evaluation of native or prosthetic valves with clinical signs or symptoms suggesting valve dysfunction, when TTE is inadequate
- Re-evaluation of known prosthetic valve dysfunction when it would change management or guide therapy, (and TTE is inadequate)

Infective Endocarditis[1,8,9]

- Suspected infective endocarditis (IE) of native valve, prosthetic valve, or endocardial lead with positive blood culture or new murmur
- Moderate to high pretest probability of IE (i.e., staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device) when TTE is negative
- 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)
- 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[1]
- Evaluation of cardiac mass, suspected tumor, or thrombus[1,9]
- Re-evaluation of prior TEE finding for interval change (e.g., resolution of thrombus after anticoagulation), when the findings would change therapy

Atrial Fibrillation/Flutter[1]

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

TAVR (Transcatheter Aortic Valve Replacement/Repair)[1,10]

- 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[1,11]

- 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[12]

- Evaluation of anatomy, potential cardiac source of emboli, and suitability for percutaneous occlusion device placement
- 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[13,14]
    - Reassessment at 6 months if 45-day TEE shows incomplete closure of left atrial appendage[13,14]

Percutaneous Mitral Valve Repair[1]

- Determination of patient eligibility for percutaneous mitral valve procedures
- Pre-procedural evaluation for percutaneous mitral valve procedures may be performed in addition to CT imaging[15]
- To exclude the presence of intracardiac mass, thrombus, or vegetation prior to (within 3 days of) the procedure

Hypertrophic Cardiomyopathy[16]

- When TTE is inconclusive in planning for myectomy,[17] to exclude subaortic membrane or mitral regurgitation, or to assess need for septal ablation

Adult Congenital Heart Disease[11,18]

- Imaging with provocative maneuvers (Valsalva, cough) to assess the presence of right-to-left cardiac shunt
- Evaluation prior to planned repair of the following lesions when TTE, CMR, or CT are not adequate:
    - Isolated secundum atrial septal defect
    - Sinus venosus defect and/or partial anomalous pulmonary venous connection
    - Congenital mitral stenosis or mitral regurgitation
    - Subvalvular aortic stenosis
    - Transposition of the Great Arteries
- 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

Ventricular Assist Devices[1,19]

- Preoperative evaluation of suitability for ventricular assist device (VAD)
- Re-evaluation of VAD-related complication or suspected infection

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BACKGROUND

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).

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

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POLICY HISTORY

Date	Summary
April 2023	• Added statement on clinical indications not addressed in this guideline
June 2022	• Updated surveillance protocol of left atrial appendage occlusion device based on FDA guidance
February 2022	• No significant changes

Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical Guidelines **STRESS ECHOCARDIOGRAPHY**	**Original Date: February 2010**
CPT Codes: 93350, 93351, +93320, +93321, +93325, +93352, +93356	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_026	**Implementation Date: January 2024**

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.*

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 Overview section).

INDICATIONS for STRES ECHO [1-3]

SUSPECTED CORONARY ARTERY DISEASE (CAD)

Symptomatic patients without known CAD (use Diamond Forrester Table)

- Low or intermediate pretest probability, and electrocardiogram (ECG) is uninterpretable
- High pretest probability
- 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 Overview section)
- Previously unevaluated pathologic Q waves (see Overview section)
- Previously unevaluated complete left bundle branch block

ABNORMAL CALCIUM SCORES (CAC)[1, 4-7]

- ASYMPTOMATIC patient with a calcium score >400, not previously evaluated
- SYMPTOMATIC patient with prior CAC ≥ 100

INCONCLUSIVE CAD EVALUATION AND OBSTRUCTIVE CAD REMAINS A CONCERN

- Exercise stress ECG with low-risk Duke treadmill score ≥5, but patient's current symptoms indicate an intermediate or high pretest probability
- Exercise stress ECG with an intermediate Duke treadmill score
- Intermediate coronary computed tomography angiography (CCTA) defined as:
  - 40 -70% lesion
- Coronary stenosis of unclear significance on previous coronary angiography[1]

FOLLOW-UP OF PATIENTS POST CORONARY REVASCULARIZATION (PCI or CABG)[8]

- **Asymptomatic, follow-up stress imaging** (MPI or SE), 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 a history of silent ischemia or a history of a prior left main stent[1]

  OR

- For patients with high occupational risk including any of the following:
  - 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 post coronary revascularization** is an indication for stress imaging

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 ≤ 0.80 or significant stenosis in a major vessel (≥ 50% left main coronary artery or ≥ 70% LAD, LCX, RCA)), over two years ago without intervening coronary revascularization, is an appropriate indication for stress imaging (MPI or SE)

SPECIAL DIAGNOSTIC CONDITIONS REQUIRING CORONARY EVALUATION

- Prior acute coronary syndrome (with documentation in MD notes), within last three 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[4, 8]
- Ventricular arrhythmias:
    - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise-induced VT, when invasive coronary arteriography has not been performed[9]
    - Nonsustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, frequent PVCs (defined as greater than or equal to 30/hour on remote monitoring), when an exercise ECG cannot be performed[9]
- 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[10]
- Hemodynamic assessment of ischemia in one of the following documented conditions:
    - Anomalous coronary arteries in an asymptomatic individual without prior stress echocardiography[11];
    - Myocardial bridging of a coronary artery[12]
- Coronary aneurysms in Kawasaki's disease[13]
- Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter[14]

CHRONIC VALVULAR DISEASE

Evaluation with Inclusion of Doppler[15-18]

- 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%
- For evaluation of asymptomatic moderate or severe aortic stenosis (AS) for measurement of changes in valve hemodynamics
- Non-severe aortic regurgitation (AR) with symptoms: Assessment of functional capacity and to assess for other causes of symptoms[8, 19]
- 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
- 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; **OR**
    - The echocardiogram is not able to distinguish whether the MR is moderate or severe in a patient that is asymptomatic

- For symptomatic patients with HCM, who do not have resting or provocable outflow tract gradient ≥50 mm Hg on TTE, for detection and quantification of dynamic LVOT obstruction[20]
- For asymptomatic patients with HCM who do not have a resting or provocable outflow tract gradient ≥ 50 mm Hg on TTE (Class 2A)

DIASTOLIC FUNCTION

- For unexplained dyspnea and suspected heart failure with preserved LVEF[19] (HFpEF) with normal or equivocal diastolic function on resting images

PRIOR TO ELECTIVE NON-CARDIAC SURGERY[2, 21-23]

- 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[21, 23, 24]
  - **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
- 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. [2, 25]

POST CARDIAC TRANSPLANTATION

- Annually, for the first five years post cardiac transplantation, in a patient not undergoing invasive coronary arteriography
- After the first five years post cardiac transplantation, patients with documented transplant coronary vasculopathy can be screened annually unless invasive coronary arteriography is planned

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BACKGROUND

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).

Stable patients without known CAD fall into 2 categories[1-3]:

- **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 3 Types of Chest Pain or Discomfort:

- **Typical Angina (Definite)** is defined as including **all 3** of these characteristics:
    - Substernal chest pain or discomfort with characteristic quality and duration, such as:
        - Pressure-like
        - Radiating
        - Dull or aching
    - Provoked by exertion or emotional stress
    - Relieved by rest and/or nitroglycerine
- **Atypical Angina (Probable)** has only **2** of the above characteristics
- **Nonanginal 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[1, 3]:

Diamond Forrester Table

Age (Years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal 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

- **Very low:** < 5% pretest probability of CAD, usually not requiring stress evaluation[3]
- **Low:** 5 - 10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High:** > 90% pretest probability of CAD

OVERVIEW

MPI may be performed without diversion to SE in any of the following[1, 26]:

- 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[1]:

- The (symptomatic) low or intermediate pretest probability patient who is able to exercise and has an interpretable ECG
- The patient who is under evaluation for exercise-induced arrhythmia[9]
- For the evaluation of syncope or presyncope during exertion[27]
- The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription.

Duke Exercise ECG Treadmill Score[28]

Calculates risk from ECG treadmill alone**:**

- The equation for calculating the Duke treadmill score (DTS) is: DTS = exercise time in minutes - (5 x ST deviation in mm or 0.1 mV increments) - (4 x 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 ≥ + 5), intermediate risk (with scores ranging from - 10 to + 4), and high-risk (with a score of ≤ -11) categories.

An uninterpretable baseline ECG includes[3]:

- ST segment depression 1 mm or more; (not for non-specific ST- T wave changes)
- Ischemic looking T wave -- at least 2.5 mm inversions (excluding V1 and V2)
- LVH, 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*

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

*Patients who have known CAD are already at high global risk and are not applicable to the calculators.[29-33]

Definitions of Coronary Artery Disease[2, 3, 5, 34, 35]

- Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and refers to cross-sectional narrowing when IVUS (intravascular ultrasound) is the method of determination
- 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 $\underline{\geq}$ 70% by angiography; intermediate lesions are 50 – 69%[36]
    - For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum lumen cross-sectional area on IVUS ≤ 6 square mm[3, 35, 37]
    - FFR (fractional flow reserve) ≤ 0.80 for a major vessel[35, 37]
- 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[3, 27, 38]

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.

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

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POLICY HISTORY

Date	Summary
May 2023	• Removed time limitation "within past two years" for further evaluation inconclusive prior CAD evaluation • Added coronary stenosis of unclear significance on coronary angiography • Added evaluation of asymptomatic moderate or severe aortic stenosis (AS) and aortic regurgitation (AR) for measurement of changes in valve hemodynamics • Added evaluation symptomatic patients with suspected diastolic dysfunction • Added statement on clinical indications not addressed in this guideline
February 2022	• Moved the sentence regarding utilization of suitable alternatives such as Stress Echocardiography and MPI to the General Information section • Clarified "intermediate lesions are 50-69%" for ischemia-producing disease • Placed Link to Overview Section in General Information • Deleted the requirement for diabetes when calcium score > 400 for stress imaging • Added Calcium score section: ○ Added stress imaging approval for calcium score > 100 with symptoms consistent with low to intermediate pretest probability • Changed preoperative guideline to include intermediate risk surgery with one or more risk factors AND documentation of an inability to walk (or <4 METs) AND there has not been an imaging stress test within 1 year • Changed solid organ transplant guideline to include stem cell transplant and "any" organ transplant • Added definition of surgical risk to preop guidelines • In Background section clarified the requirement for description of chest pain by adding sentence "The medical record should provide enough detail to establish the type of chest pain. " • Added definition of Q waves • Deleted sentence regarding calcium scoring within the Global Risk Section • Deleted sentence regarding using calcium score solely for risk stratification • Deleted IFR references

Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guidelines **HEART CATHETERIZATION**	**Original Date: February 2010**
CPT Codes: 93452, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, +93462, +93463, +93464, +93565, +93566, +93567, +93568	**Last Revised Date: April 2023**
Guideline Number: NIA_CG_065	**Implementation Date: January 2024**

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.*

INDICATIONS FOR INVASIVE CORONARY ARTERIOGRAPHY[1-5]

General

- Typical angina with new onset or evolving ischemic EKG changes
- New onset or worsening of the patient's previously known anginal symptoms in a patient with a history of CABG or PCI
- Symptomatic patients with a high pretest probability
- Unheralded syncope (not near syncope), where the etiology is unclear

Stable Ischemic Heart Disease

- Exercise electrocardiogram (ECG) stress test with high-risk findings, such as Duke Score ≤ -11, ST segment elevation, hypotension, exercise-induced ventricular tachycardia (VT), or several minutes of ST segment depression post exercise[3]
- Stress imaging with high-risk findings (see Background section)
- Stress imaging with intermediate risk findings (see Background section) in a patient with one of the following:

    - Symptoms consistent with ischemia[3]
    - Unsatisfactory quality of life due to angina[2]
    - Ejection fraction (EF) < 50%[2]
- Non-invasive test with low-risk findings with new, worsening, or limiting symptoms with reasonable suspicion of cardiac origin despite optimal medical therapy (OMT) or inability to tolerate OMT[1-3]
- New, worsening, or limiting symptoms, with known unrevascularized obstructive coronary artery disease (CAD), in a patient eligible for revascularization[1, 2]
- Post STEMI with "culprit only" revascularization and plan for further PCI of non-culprit lesion[6]
- Discordant, equivocal, or inconclusive non-invasive evaluation in patients with suspected symptomatic stable ischemic heart disease, including the following[3, 5, 7]:
    - Low risk stress imaging with high-risk stress ECG response or stress induced typical angina[3]
    - Equivocal, uninterpretable, or inconclusive stress imaging due to issues of attenuation or other problems with interpretability[2, 3]

CCTA Abnormalities

- Symptomatic patient with one of the following[2-4]:
    - One vessel with ≥ 50% stenosis
    - A stenosis of 40-90% and FFR-CT ≤0.8[8]
    - ≥ 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[2, 3, 5, 9, 10]:
    - Newly recognized heart failure in patients with known or suspected CAD
    - Symptomatic heart failure or ischemia with new, unexplained wall motion abnormality[2, 3]
    - 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[11]

Ventricular Arrhythmias

- Ventricular arrhythmias, without identified non-cardiac cause:
    - Following recovery from unexplained sudden cardiac arrest[12]
    - Sustained VT or VF[3]
    - Exercise-induced VT[3]

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[13-17]:
    - 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
    - Chronic severe secondary mitral regurgitation
    - 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[18]
- 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[19]

- Assessment for allograft vasculopathy annually for the first 5 years, followed by annual assessment in those with documented allograft vasculopathy, if stress imaging has not been performed
- Assessment of change in clinical status, including any of the following, if stress imaging has not been performed:
    - New left ventricular dysfunction
    - Symptoms of ischemia
    - Non-invasive findings of ischemia

Hemodynamic Assessment

- Indications for angiographic and/or hemodynamic assessment of valvular function or shunt physiology[3, 13, 20]

    - 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[3, 20]
    - 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

These guidelines only cover procedures that include left heart catheterization. NIA does not manage right heart catheterization as a stand-alone procedure.

BACKGROUND

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 ≥70% (≥50% in the left main coronary artery) is considered clinically significant or obstructive CAD.[2, 5, 7, 21]

This guideline applies to patients with a stable clinical presentation, not to those with acute coronary syndromes or acute valvular abnormalities.

In stable patients, preliminary evaluation with non-invasive cardiac testing is usually indicated prior to a recommendation for cardiac catheterization.

Stable Patients without Known CAD fall into 2 categories[2, 5, 7]:

- **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

Once the type of chest pain has been established from the medical record, 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.[2, 5]

Diamond Forrester Table

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[2, 4]

- **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[22]
- 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
  - ≥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)[2, 3, 7, 23]
  - One vessel CAD with ≥ 70% stenosis or moderate CAD stenosis (50% to 69% stenosis) in ≥ 2 arteries on CCTA

- **Low risk (< 1% annual death or MI)**
  - Low-risk treadmill score (score ≥ 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)[2, 3, 7, 23]
  - 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. **High global risk by itself generally lacks scientific support as an indication for stress imaging**.[24] 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.

- **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*

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

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.[23, 25-28]

Definitions of Coronary Artery Disease[2, 4, 7, 29]

- 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 ≥ 70% by angiography; intermediate lesions are 50 – 69%[30]
    - For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum luminal cross-sectional area on IVUS ≤ 6 square mm[2, 21, 29]
    - FFR (fractional flow reserve) ≤ 0.80 for a major vessel[21, 29]
    - iFR (instantaneous wave-free ratio) ≤ 0.89 for a major vessel[21, 31-33]
- 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 ≤ 0.89 considered hemodynamically significant.[31-33]

Anginal Equivalent[2, 34, 35]

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

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

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POLICY HISTORY

Date	Summary
April 2023	• Added definition of unstable angina to include ischemic EKG changes • Added definition in background section on OMT (optimal medical therapy) • Added indication for revascularization of non-culprit lesion post STEMI • Added statement on clinical indications not addressed in this guideline
February 2022	• Added indications to CCTA section regarding left main disease, single vessel disease >50% stenosis • Modified indication for exercise-induced VT removing statement "requiring signs and symptoms of ischemia" • Clarified definition of intermediate findings, non-invasive testing • FFR-CT statement updated • Modified indication for newly diagnosed HF removing statement "requiring signs and symptoms of ischemia"

Reviewed / Approved by NIA Clinical Guideline Committee

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