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HEART CATHETERIZATION	
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+93464, +93565, +93566, +93567, +93568	
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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 ARTERIOGRAPHY1-5

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 exercise³
- Stress imaging with high-risk findings (see <u>Background</u> section)
- Stress imaging with intermediate risk findings (see <u>Background</u> section) in a patient with one of the following:

- Symptoms consistent with ischemia³
- Unsatisfactory quality of life due to angina²
- 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 OMT¹⁻³
- 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 lesion⁶
- 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 angina³
 - 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 following²⁻⁴:
 - One vessel with ≥ 50% stenosis
 - A stenosis of 40-90% and FFR-CT ≤0.88
 - ≥ 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 syndrome¹¹

Ventricular Arrhythmias

- Ventricular arrhythmias, without identified non-cardiac cause:
 - Following recovery from unexplained sudden cardiac arrest¹²
 - Sustained VT or VF³
 - Exercise-induced VT³

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 following¹³⁻¹⁷:
 - 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
 - o 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 recommended¹⁸
- 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 Transplantation¹⁹

- 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
 - o 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. Evolent 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 <u>Global Cardiovascular Risk Calculators</u> section).

Page **4** of **15** Heart Catheterization • **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
120	Men	Intermediate	Intermediate	Low
≤ 39	Women	Intermediate	Very low	Very low
40 40	Men	High	Intermediate	Intermediate
40 – 49	Women	Intermediate	Low	Very low
FO FO	Men	High	Intermediate	Intermediate
50 – 59	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
 - \circ Resting perfusion abnormalities \geq 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 exerciseinduced 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 > 1.12²²
- 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 exerciseinduced 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
- o 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	https://reference.medscape.com/calculator/framingham-	
Cardiovascular Risk	<u>cardiovascular-disease-risk</u>	
Reynolds Risk Score	http://www.reynoldsriskscore.org/	
Can use if no diabetes		
Unique for use of		
family history		
Pooled Cohort	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example	
Equation		
ACC/AHA Risk	http://tools.acc.org/ASCVD-Risk-Estimator/	
Calculator		
MESA Risk Calculator	https://www.mesa-	
With addition of	nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx	
Coronary Artery		
Calcium Score, for		
CAD-only risk		

^{*}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 \geq 70% by angiography; intermediate lesions are $50 69\%^{30}$
 - For a left main artery, suggested by a percentage stenosis \geq 50% or minimum luminal cross-sectional area on IVUS \leq 6 square mm^{2, 21, 29}
 - FFR (fractional flow reserve) \leq 0.80 for a major vessel^{21, 29}
 - o 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)

EF 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 Clinical Guideline Committee

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