

EVOLENT CLINICAL GUIDELINE 065 FOR HEART CATHETERIZATION

Guideline or Policy Number:	Applicable Codes		
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TABLE OF CONTENTS

STATEMENT	3
GENERAL INFORMATION PURPOSE CLINICAL REASONING	3 3 3
INDICATIONS FOR INVASIVE CORONARY ARTERIOGRAPHY	4
General Stable Ischemic Heart Disease	4 4
CCTA Abnormalities	5
Ventricular Arrhythmias	5
Hypertrophic Cardiomyopathy	6
Hemodynamic Assessment	7
INDICATIONS FOR ASCENDING AURIOGRAPHT	
	0
CODING AND STANDARDS	8
CODING AND STANDARDS	8
CODING AND STANDARDS	8 8 8
CODING AND STANDARDS CODING <i>CPT Codes</i> APPLICABLE LINES OF BUSINESS	8 8 8 8 8
CODING AND STANDARDS CODING CPT Codes APPLICABLE LINES OF BUSINESS BACKGROUND AUC Score	8 8 8 8 8 8
CODING AND STANDARDS CODING. CPT Codes APPLICABLE LINES OF BUSINESS. BACKGROUND AUC Score Definitions	8 8 8 8 8
CODING AND STANDARDS CODING CPT Codes APPLICABLE LINES OF BUSINESS BACKGROUND AUC Score Definitions Acronyms / Abbreviations POLICY HISTORY	8 8 8 8 8 8 8 8 8 9 13 14
CODING AND STANDARDS CODING CPT Codes APPLICABLE LINES OF BUSINESS BACKGROUND AUC Score Definitions Acronyms / Abbreviations POLICY HISTORY Summary	8 8 8 8 8 8 8 9 13 13 14 14
CODING AND STANDARDS CODING CPT Codes APPLICABLE LINES OF BUSINESS BACKGROUND AUC Score Definitions Acronyms / Abbreviations POLICY HISTORY Summary LEGAL AND COMPLIANCE	8 8 8 8 8 8 8 9 13 14 14 14

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DISCLAIMER	15	5
REFERENCES	16	3



STATEMENT

General Information

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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

Purpose

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

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

CLINICAL REASONING

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

In instances where an AUC has not been established through prior publication, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(5,6,7,8,9)



INDICATIONS FOR INVASIVE CORONARY ARTERIOGRAPHY (1,10,11,12)

General

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

Stable Ischemic Heart Disease

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

Page 4 of 19



- Discordant, equivocal, or inconclusive non-invasive evaluation in patients with suspected symptomatic stable ischemic heart disease, including the following: ^(3,4,11)
 - Low risk stress imaging with high-risk stress ECG response or stress induced typical angina ⁽¹¹⁾
 - Equivocal, uninterpretable, or inconclusive stress imaging due to issues of attenuation or other problems with interpretability ^(1,11)

CCTA Abnormalities

- Symptomatic patient with one of the following: (1,11,12)
 - One vessel with \geq 50% stenosis (AUC 7) ⁽⁴⁾
 - A stenosis of 40-90% and FFR-CT ≤0.8⁽¹⁴⁾ (AUC 8)⁽⁴⁾
 - ≥ 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 ^(1,4,11,15) (AUC 8) ⁽⁴⁾
 - Newly recognized heart failure in patients with known or suspected CAD
 - Symptomatic heart failure or ischemia with new, unexplained wall motion abnormality ^(1,11)
 - 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
 - $\circ~$ Clarification of the diagnosis of myocarditis versus acute coronary syndrome $_{\scriptscriptstyle (17)}$

Ventricular Arrhythmias

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



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: ^(19,20,21,22)
 - 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
 - o Chronic severe secondary mitral regurgitation
 - Severe valve disease
 - Requirement for detailed assessment of coronary artery anatomy prior to aortic valve homograft surgery, pulmonary autograft (Ross procedure), or aortic root procedure
 - Patients undergoing transcatheter aortic valve replacement (TAVR) or other transcatheter valve procedures
 - Can be done pre-organ transplant when required by transplant center protocol in place of, but not in addition to an imaging study

Hypertrophic Cardiomyopathy

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

Post Cardiac Transplantation

Assessment for allograft vasculopathy annually for the first 5 years, followed by annual assessment in those with documented allograft vasculopathy, if stress imaging has not been performed.⁽²⁴⁾

- 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

Page 6 of 19



Hemodynamic Assessment

- Indications for angiographic and/or hemodynamic assessment of valvular function or shunt physiology ^(11,19,25)
 - 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 (11,25)
 - Assessment of constrictive and restrictive physiology
 - Assessment of pulmonary hypertension when non-invasive data provides inadequate information for management, or to evaluate response to intravenous drug therapy
 - Assessment of hemodynamics in heart failure, cardiomyopathy, or adult congenital heart disease, when
 - Non-invasive data is discordant or conflicts with the clinical presentation
 - Non-invasive data is inadequate for clinical management

INDICATIONS FOR ASCENDING AORTOGRAPHY (19,21,22)

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



CODING AND STANDARDS

Coding

CPT Codes

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

Applicable Lines of Business

\boxtimes	CHIP (Children's Health Insurance Program)
\boxtimes	Commercial
\boxtimes	Exchange/Marketplace
\boxtimes	Medicaid
\square	Medicare Advantage

BACKGROUND

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.

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

AUC Score

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

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

Page 8 of 19



Definitions

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

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

Diamond Forrester Table (26,27)

Low: 5 - 10% pretest probability of CAD

Intermediate: 10% - 90% pretest probability of CAD

Page 9 of 19



High: > 90% pretest probability of CAD

- Coronary Risk Categories Derived from Non-invasive Testing ^(1,12)
 - 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%)</p>
 - 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 ⁽²⁸⁾
 - 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)</p>
 - 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) ^(1,3,11,29)

Page 10 of 19



- 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) ^(1,3,11,29)
 - No coronary stenosis > 50% on CCTA
- Global Risk of Cardiovascular Disease
 - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years.
 - CAD Risk—Low
 - □ 10-year absolute coronary or cardiovascular risk less than 10%
 - CAD Risk—Moderate
 - 10-year absolute coronary or cardiovascular risk between 10% and 20%
 - CAD Risk—High
 - 10-year absolute coronary or cardiovascular risk of greater than 20%
 - NOTE: High global risk by itself generally lacks scientific support as an indication for stress imaging ⁽³⁰⁾. 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.

Risk Calculator	Websites for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham- cardiovascular-disease-risk
Reynolds Risk Score	http://www.reynoldsriskscore.org/
Can use if no diabetes	

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

Page 11 of 19



Risk Calculator	Websites for Online Calculator
Unique for use of family history	
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.

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

Page 12 of 19



- 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. ^(36,37,38)
- Anginal Equivalent (1,39,40)
 - Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry, lung exam, etc. (as well as D-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.
- Optimal Medical Therapy (OMT)
 - In general, a trial of OMT includes
 - Anti-platelet therapy
 - Lipid-lowering therapy
 - Beta blocker
 - Angiotensin converting enzyme (ACE) inhibitor

Acronyms / Abbreviations

CABG: Coronary artery bypass grafting surgery CAC: Coronary artery calcium CAD: Coronary artery disease CCT: Cardiac computed tomography CCTA: Coronary computed tomographic angiography CMR: Cardiac magnetic resonance CT(A): Computed tomography (angiography) ECG: Electrocardiogram EF: Ejection fraction FFR: Fractional flow reserve FFR-CT: Fractional flow reserve - computed tomography HCM: Hypertrophic cardiomyopathy iFR: Instantaneous wave-free ratio IVUS: Intravascular ultrasound LV: Left ventricular LVEF: Left ventricular ejection fraction LVOT: Left ventricular outflow tract

Page 13 of 19



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

POLICY HISTORY

Summary

Date	Summary
February 2024	 Formatting change Addition of clinical reasoning statement with AUC scoring described AUC scores added to bullet points Indications for Ascending Aortography added
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

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by NIAEvolent Specialty Clinical Guideline Review Committee



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Page 16 of 19



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Page 17 of 19



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Page 18 of 19



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