

Cardiac Catheterization and Angiography

ACG: A-0001 (AC)

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MCG Health
Ambulatory Care
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Clinical Indications

- Cardiac catheterization and angiography may be indicated for **1 or more** of the following:
 - Cardiac transplant patient, for surveillance of cardiac allograft vasculopathy and acute rejection following transplant(11)(12)(13)(14)[N](#)
 - ☐ Congenital heart disease, known or suspected, as indicated by **1 or more** of the following(1)(16)(17)(18):[N](#)
 - Coronary anomaly, known or suspected(19)(20)(21)
 - Direct measurement of pressure gradients or oxygen saturations needed (eg, for intracardiac shunt, valvular heart disease)(22)(23)(24)
 - Invasive procedure planned, and preoperative or postoperative catheterization or angiographic imaging needed (eg, for pressure and gradient measurements)(23)(25)
 - Noninvasive imaging is nondiagnostic or discordant with physical examination findings.(19)(24)
 - Supravalvular aortic stenosis, known, and coronary imaging needed due to symptoms of coronary ischemia (eg, angina, dyspnea, syncope, arrhythmia)

- ☐ Coronary artery disease, known or suspected, as indicated by **1 or more** of the following(2)(6)(13)(14)(26)(27)(28):^[1]
- Angina at rest or crescendo angina (ie, unstable angina), and noninvasive stress imaging is unavailable, contraindicated, or nondiagnostic(46)(49)(50)
 - Angina recurrent within 9 months of percutaneous coronary intervention
 - Evidence of high risk based on noninvasive testing, as indicated by **1 or more** of the following(32)(33)(46)(51)(52):
 - Cardiac CT angiography-defined disease, as indicated by **1 or more** of the following:
 - Left main coronary artery with 50% or greater stenosis(53)
 - Obstructive coronary artery disease with CT-derived fractional flow reserve of 0.8 or less
 - Severe (70% or greater) stenosis in 3 main vessels
 - Cardiogenic shock, known or suspected, as indicated by **ALL** of the following(54)(55):
 - Signs and symptoms of circulatory shock, as indicated by **1 or more** of the following:
 - Altered mental status
 - Elevated serum lactate level (2.0 mmol/L (18 mg/dL) or more)
 - Hypotension
 - Metabolic acidosis (arterial or venous pH less than 7.35) not otherwise explained
 - Respiratory rate greater than 20 breaths per minute
 - Tachycardia
 - Urine output less than 0.5 mL/kg/hr
 - Signs and symptoms of heart failure (eg, dyspnea, orthopnea, pulmonary or peripheral edema, cyanosis)
 - Coronary artery calcium score at least 100 Agatston units, or at least 75th percentile for age, sex, and ethnicity(56)
 - Duke Treadmill Score less than or equal to -11[A]
 - Echocardiographic wall motion abnormality involving greater than 2 segments, developing at dobutamine dose of less than 10 mcg/kg per minute or at heart rate less than 120 beats per minute
 - Left ventricular ejection fraction 40% or less at rest
 - Perfusion imaging shows evidence of global ischemia or large territory of myocardium at risk.
 - Stress electrocardiogram findings of ST-segment elevation, ventricular arrhythmia, or at least 2 mm of ST-segment depression(58)
 - Stress-induced large perfusion defect or multiple moderate perfusion defects
 - Stress-induced left ventricular dysfunction
 - Transient ischemic dilation
 - Following myocardial infarction and during risk-stratification phase, and **1 or more** of the following:
 - Clinically significant heart failure during hospital course
 - Ischemia at low level of exercise on noninvasive testing
 - Left ventricular ejection fraction 45% or less, and patient unable to undergo noninvasive testing
 - Treated with fibrinolytic therapy, and invasive treatment strategy planned(3)(33)(58)
 - Ischemia recurrent (by clinical or noninvasive testing) within 12 months of coronary artery bypass graft(59)
 - Non-ST-elevation coronary syndrome, and invasive strategy determined(33)(51)(58)
 - Occupation of patient directly involves safety of others (eg, bus driver, pilot, firefighter), and **1 or more** of the following(60)(61):
 - Abnormal results on noninvasive testing
 - Risk factors for coronary artery disease[B]
 - Pericarditis (acute), suspected, when signs and symptoms, troponin levels, and pattern of ST elevation cannot definitively rule out acute infarction
 - Prinzmetal (variant) angina, suspected(44)(46)
 - Progressive abnormalities on noninvasive testing(33)
 - Resuscitation of patient from cardiac arrest or ventricular tachycardia(64)(65)(66)

- Risk stratification required (eg, prior to high-risk noncardiac surgery) in patient who cannot undergo noninvasive testing due to disability or illness
- Stent thrombosis, suspected, either abrupt closure or subacute, following percutaneous coronary intervention(3)(67)(68)
- Coronary artery dissection, spontaneous, suspected(69)(70)(71)[\[N\]](#)
- ☐ Heart failure, known or suspected, as indicated by **1 or more** of the following(67)(75)(76)(77)(78):[\[N\]](#)
 - Associated with angina or anginal equivalent
 - Constrictive pericarditis(79)
 - Episodic heart failure with preserved ejection fraction on noninvasive testing
 - Left ventricular ejection fraction less than 45%, unexplained by noninvasive testing(13)(80)
 - Post myocardial infarction, when left ventricular ejection fraction 35% or less
 - Postmyocardial infarction ventricular aneurysm(81)
 - Preoperative planning needed before cardiac transplant or mechanical circulatory support
 - Restrictive cardiomyopathy(82)
 - Reversible ischemia on stress echocardiogram or myocardial perfusion imaging, and revascularization (ie, coronary artery bypass graft, percutaneous coronary intervention) being considered
 - Wall motion abnormality involving more than 2 segments with low-dose dobutamine or at heart rate less than 120 beats per minute
- ☐ Hypertrophic cardiomyopathy, known or suspected, as indicated by **1 or more** of the following(83)(84):[\[N\]](#)
 - Coronary artery disease suspected, as indicated by **ALL** of the following:
 - Chest discomfort in setting of intermediate to high likelihood of coronary artery disease
 - Identification of coronary artery disease will affect management.
 - Measurement of left ventricular outflow gradient needed due to equivocal or discordant results on noninvasive testing(82)
 - Septal reduction therapy needed (eg, alcohol septal ablation, surgical myectomy)(85)
- Kawasaki disease, known(86)(87)[\[N\]](#)
- ☐ Pulmonary artery extrinsic compression of left main coronary artery, known or suspected, as indicated by **ALL** of the following(6):[\[N\]](#)
 - Ischemic heart disease, as indicated by anginal symptoms or abnormal left ventricular function
 - Longstanding pulmonary hypertension(22)
- Pulmonary hypertension, known or suspected(22)(88)(89)(90)(91)(92)(93)[\[N\]](#)
- ☐ Valvular heart disease, known or suspected, as indicated by **1 or more** of the following(102)(103):[\[N\]](#)
 - Atrial myxoma, when transesophageal echocardiography is indeterminate
 - Mild to moderate valvular heart disease, as indicated by **1 or more** of the following:
 - Canadian Cardiovascular Society class II, III, or IV angina[C]
 - Ejection fraction 45% or less
 - Heart failure
 - Ischemia documented by noninvasive testing
 - Noninvasive test results are inconclusive, inconsistent, or discordant with patient symptoms.(52)
 - Patient is symptomatic, and echocardiographic findings are equivocal with regard to severity of valve disease.(52)
 - Preoperative, preprocedural, or intraprocedural planning needed for indicated valve surgery, transcatheter valve replacement or repair, or mitral balloon valvuloplasty, as indicated by **1 or more** of the following(46)(105):
 - Age or menopausal status, as indicated by **1 or more** of the following:
 - Male patient age 40 years or older
 - Postmenopausal female patient
 - Coronary artery disease, known or suspected (due to risk factors, symptoms, or noninvasive testing)[B]
 - Ejection fraction less than 55%

- Percutaneous mitral valve repair, and need to evaluate concomitant coronary artery disease
- Transcatheter aortic valve replacement, and need to evaluate concomitant coronary artery disease(106)
- Transcatheter tricuspid valve procedure, and need to screen for pulmonary hypertension(99)(100)(101)
- Preoperative planning needed before Ross procedure to identify coronary orifices if not identified noninvasively
- Severe aortic or mitral regurgitation on echocardiography, as indicated by **1 or more** of the following[D]:
 - Aortic regurgitation diagnosed as severe on echocardiography, as indicated by **1 or more** of the following:
 - Doppler jet width 50% or greater of left ventricular outflow tract
 - Effective regurgitant orifice 0.3 cm² or greater
 - Holodiastolic aortic flow reversal
 - Left ventricular dilation
 - Left ventricular ejection fraction less than 55%
 - Regurgitant fraction 50% or greater
 - Regurgitant volume 60 mL per beat or greater
 - Vena contracta 0.6 cm or greater
 - Mitral regurgitation diagnosed as severe on echocardiography, as indicated by **1 or more** of the following(46)(103):
 - Effective regurgitant orifice 0.4 cm² or greater
 - Left ventricular dilation
 - Left ventricular ejection fraction 60% or less
 - Left ventricular end-systolic dimension 40 mm or greater
 - Regurgitant fraction 50% or greater
 - Regurgitant volume 60 mL or greater
 - Vena contracta 0.7 cm or greater
 - Physical examination findings discordant with echocardiographic or other noninvasive imaging findings
 - Pulmonary hypertension
- ☐ Repeat evaluation of specific area or structure with same imaging modality, and **ALL** of the following:
 - Clinical need for repeat imaging, as indicated by **1 or more** of the following:
 - Change in clinical status (eg, worsening symptoms or new associated symptoms), and findings may impact treatment
 - Need for interval reassessment that may impact treatment plan
 - Need for re-imaging either prior to or after performance of invasive procedure
 - Prior imaging results of specific area or structure with same imaging modality documented and available for comparison

Evidence Summary

Background

Cardiac catheterization and angiography is an invasive procedure that includes fluoroscopy after injection of contrast material via catheter into the great vessels, chambers, and coronary vessels of the heart, as well as saphenous vein grafts and arterial bypass grafts or other arterial conduits such as the mammary arteries. In addition to demonstrating areas of stenotic, regurgitant, or otherwise abnormal blood flow, coronary angiography with left and right heart catheterization or left ventriculography enables quantitative assessment of myocardial function, such as left ventricular ejection fraction, cardiac output, or degree of shunting.(1) (**EG 2**) It also enables quantitative assessment of coronary blood flow.(2) (**EG 2**) Invasive coronary angiography remains the gold standard for visualization and characterization of the coronary anatomy.(3)(4)(5) (**EG 2**) However, radiation exposure and nephrotoxicity from contrast material are significant factors that limit the duration and frequency of angiography.(6)(7)(8)(9) (**EG 2**)

Criteria

The evidence for the clinical indications found in this guideline includes 77 published peer reviewed articles, 23 specialty society or other evidence-based guidelines, and 7 book sections.

For cardiac transplant patients, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** It has been noted that a major cause of death in post-transplant patients is coronary artery vasculopathy, and cardiac catheterization with intravascular ultrasound is useful for surveillance of cardiac allograft vasculopathy and silent obstructive coronary artery disease.(11)(15) **(EG 2)** Right heart catheterization is useful for hemodynamic assessment in post-transplant patients and to facilitate endomyocardial biopsy to provide histologic monitoring for transplant rejection.(15) **(EG 2)**

For congenital heart disease, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** The availability of noninvasive imaging has made angiography less important for diagnosis.(1)(16)(19) **(EG 2)** However, it is indicated in both children and adults before surgery when repair may involve the coronary arteries or because of chest pain. It may also be indicated for complex congenital heart disease, particularly when intracardiac shunting is present.(16) **(EG 2)** A specialty society guideline notes that cardiac catheterization and coronary angiography may be indicated for accurate measurement of congenital pulmonary or aortic stenosis gradients and to delineate anatomy, as well as for accurate assessment of pulmonary artery pressure and pulmonary vascular resistance. Pulmonary angiography and right ventriculography are recommended for pulmonary stenosis in particular. For patients with repaired tetralogy of Fallot, coronary artery compression testing (via cardiac catheterization) is recommended prior to transcatheter valve replacement or right ventricle-to-pulmonary artery conduit stenting. For transposition of the great arteries, the authors note that it is reasonable to perform anatomic evaluation of coronary artery patency in asymptomatic adults following an arterial switch procedure; coronary angiography is recommended if this patency cannot be established noninvasively. Cardiac catheterization can also be useful in the assessment of coarctation and recoarctation of the aorta, of sinus venosus defects and coronary anomalies, and of vascular rings.(17) **(EG 2)**

For coronary artery disease, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Coronary angiography is indicated for evaluation of stable angina when symptoms cannot be medically controlled, are disabling, and when interventional treatment has been proposed as the next form of therapy.(13)(14) **(EG 2)** Specialty society guidelines recommend coronary angiography for risk assessment in patients with chronic coronary disease in whom clinical characteristics and noninvasive testing results suggest a high likelihood of severe disease when such patients are amenable to and are candidates for coronary revascularization.(13)(14)(29) **(EG 2)** A systematic review and meta-analysis of 16 trials including 7814 patients undergoing cardiac catheterization and angiography compared intravascular imaging-guided percutaneous coronary intervention (PCI) (9 trials exclusively used intravascular ultrasound, 4 exclusively used optical coherence tomography, and 3 used both) with angiography-guided PCI and found, at a weighted mean follow-up of 28.8 months, that intravascular imaging-guided PCI was associated with lower risk of major adverse cardiac events, cardiac death, stent thrombosis, and target-lesion revascularization compared with angiography-guided PCI.(30) **(EG 1)** Coronary angiography by cardiac catheterization allows for the use of fractional flow reserve (FFR), which is a useful tool for determining the hemodynamic significance of coronary lesions, particularly those of intermediate severity.(3) **(EG 2)** A randomized controlled trial of 1682 patients with coronary angiography showing intermediate stenosis in a target vessel compared FFR-guided with intravenous ultrasound-guided (IVUS-guided) angiography for PCI and found, at 24-month follow-up, that the primary composite outcome (death from any cause, myocardial infarction, or any revascularization) occurred in 8.1% and 8.5% of patients in the FFR-guided and IVUS-guided procedures, respectively; the authors concluded that FFR guidance is noninferior to IVUS guidance for PCI in patients with intermediate coronary stenosis.(31) **(EG 1)** Specialty society guidelines recommend that FFR should be used to guide decisions on PCI in patients with obstructive coronary artery disease and stable chest pain or patients with angina, undocumented ischemia, and angiographically intermediate stenoses; for FFR greater than 0.8, PCI is not recommended.(3)(32) **(EG 2)** A specialty society guideline recommends an invasive management strategy with cardiac catheterization and angiography for patients with non-ST-elevation acute coronary syndrome who are at intermediate or high risk of ischemic events and are suitable candidates for revascularization.(33) **(EG 2)** A randomized trial of 496 patients with non-ST-elevation acute coronary syndrome compared acute coronary angiography (within 2 hours of diagnosis) with subacute coronary angiography (within 72 hours of diagnosis) and found, at 1-year follow-up, no difference between the groups in all-cause mortality, recurrent myocardial infarction, or admission for ischemia or heart failure.(34) **(EG 1)** A randomized trial of 2147 patients with non-ST-elevation acute coronary syndrome compared early coronary angiography (within 12 hours of diagnosis) with standard care coronary angiography (within 48 to

72 hours of diagnosis) and found, at a median follow-up of 4.3 years, no difference between the groups in all-cause mortality, nonfatal recurrent myocardial infarction, or hospitalization for refractory ischemia or heart failure.(35) **(EG 1)** In a post hoc analysis of a randomized trial of 4071 patients with non-ST-elevation myocardial infarction who underwent coronary angiography, earlier performance of coronary angiography (within 12 hours after admission) was associated with a lower risk of ischemic outcomes at 180 days.(36) **(EG 1)** Coronary angiography is indicated when noninvasive imaging suggests the possibility of left main coronary artery stenosis or severe multivessel disease, or to guide percutaneous interventions.(6)(14) **(EG 2)** A systematic review and meta-analysis of 9 randomized trials (2429 patients age 75 years or older) comparing management of non-ST-elevation myocardial infarction with either invasive management (cardiac catheterization and angiography with subsequent revascularization as needed) or conservative management (optimal medical therapy with selective catheterization as needed) found, at a mean follow-up of 21 months, that invasive management was associated with a decreased risk of future myocardial infarction and revascularization compared with conservative management, with no difference in all-cause or cardiovascular mortality seen between the groups. The authors noted that the relative lack of studies in older patients, especially those with multimorbidity and frailty, limited the generalizability of the results, and future studies were recommended.(37) **(EG 1)** A randomized controlled trial of 1518 patients age 75 years or older with non-ST-elevation myocardial infarction compared an invasive management strategy (cardiac catheterization and angiography and revascularization combined with optimal medical therapy) with a conservative strategy (optimal medical therapy alone) and found, at a median follow-up of 4.1 years, that rates of cardiovascular death and nonfatal myocardial infarction were similar between the 2 groups.(38) **(EG 1)** Several risk scoring systems and clinical prediction tools have been created to help differentiate patients who are likely to have significant obstructive disease on coronary angiography from those who are not, as well as to help determine the optimal revascularization strategy and clinical outcomes.(39)(40)(41) **(EG 2)** Specialty society guidelines state that calculation of the Society of Thoracic Surgeons and SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) scores is reasonable in patients who have unprotected left main coronary artery lesions and complex coronary artery disease.(3) **(EG 2)** A cohort study involving 903 patients previously randomized to PCI found that the residual SYNTAX score was a powerful indicator of 5-year mortality, with a residual SYNTAX score (as determined by coronary angiography) of greater than 8 being associated with an all-cause mortality of 35.3% at 5 years.(42) **(EG 2)** An observational study of 37,674 patients undergoing elective coronary angiography found that the presence of nonobstructive coronary artery disease, as compared with no apparent coronary artery disease, was predictive of 1-year risk of myocardial infarction and all-cause mortality.(43) **(EG 2)** It has been noted that coronary angiography with provocative testing is the gold standard for diagnosis of coronary spasm with variant angina.(6)(44)(45)(46) **(EG 2)** A prospective study of 921 patients concluded that the intracoronary acetylcholine provocation test is a safe technique for assessment of coronary vasomotor function.(47) **(EG 2)** A meta-analysis comparing early coronary angiography with selective (late or no) angiography in patients resuscitated after out-of-hospital cardiac arrest found that, although nonrandomized studies have reported improved survival with an early angiography approach, there was no improvement in survival when the analysis was limited to randomized studies only.(48) **(EG 1)**

For coronary artery dissection occurring spontaneously, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Spontaneous coronary artery dissection has been found in 0.2% to 4% of patients with acute coronary syndrome undergoing invasive coronary angiography.(72)(73) **(EG 2)** A systematic review of 132 published case reports found that spontaneous coronary artery dissection affected a predominantly female population (36% of which occurred during pregnancy) and was confirmed by coronary angiography in 100% of patients.(74) **(EG 2)** A review article notes that invasive coronary angiography remains the first-line diagnostic tool for the evaluation of spontaneous coronary artery dissection, primarily because the majority of cases present clinically as acute coronary syndromes.(69)(71) **(EG 2)** Appropriate-use criteria endorsed by multiple specialty societies note that diagnostic coronary angiography is indicated for the evaluation of suspected coronary artery dissection.(67) **(EG 2)**

For heart failure or cardiomyopathy, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Specialty society guidelines state that cardiac catheterization and coronary angiography are appropriate for the evaluation of ischemia in heart failure patients.(67)(75)(76) **(EG 2)** A specialty society guideline indicates that right heart catheterization with a pulmonary artery catheter is recommended in patients with severe heart failure who are being evaluated for heart transplant or mechanical circulatory support.(77) **(EG 2)**

For hypertrophic cardiomyopathy, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society guideline states that cardiac catheterization and coronary angiography are useful for the evaluation of left ventricular outflow gradient (eg, with isoproterenol infusion), for the evaluation of suspected coronary artery disease, and for the performance of alcohol septal ablation and surgical myectomy in patients with obstructive hypertrophic cardiomyopathy.(83) **(EG 2)**

For Kawasaki disease, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Kawasaki disease is associated with coronary artery aneurysms, for which coronary angiography is useful for definitive imaging of the coronary arteries and great vessels.(86)(87) **(EG 2)** A specialty society guideline states that coronary angiography should be performed in patients with Kawasaki disease who are known to have medium or giant aneurysms during the convalescent phase or later in order to monitor for development or progression of localized stenoses, because myocardial ischemia due to Kawasaki disease cannot be fully detected by other imaging modalities and may manifest as sudden cardiac death.(86) **(EG 2)** A specialty society consensus statement notes that, although invasive coronary angiography is rarely performed during the acute phase of Kawasaki disease, angiography can be useful for later identification and periodic surveillance of coronary artery aneurysms, particularly when signs of ischemia are present.(87) **(EG 2)**

For pulmonary artery extrinsic compression of the left main coronary artery, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Coronary angiography is noted to be a highly accurate imaging procedure to delineate arterial anatomy, including extrinsic compression.(6) **(EG 2)**

For pulmonary hypertension, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Review articles note that right heart catheterization is useful for the measurement of pulmonary artery pressures and right heart hemodynamics, and for the evaluation of potential response to treatment (ie, vasoreactivity testing).(89)(94)(95) **(EG 2)** A systematic comparative effectiveness review notes that right heart catheterization is the gold standard for diagnosing pulmonary arterial hypertension.(88) **(EG 2)** A specialty society guideline states that right heart catheterization with a pulmonary artery catheter should be considered in patients with heart failure with probable pulmonary hypertension diagnosed by echocardiography before correction of underlying valvular or structural heart disease.(77) **(EG 2)** A scientific statement endorsed by multiple specialty societies recommends right heart catheterization for diagnostic confirmation of pulmonary hypertension in renal and liver transplant candidates if preoperative transthoracic echocardiography shows evidence of elevated pulmonary arterial pressures.(96) **(EG 2)** In pediatric patients with bronchopulmonary dysplasia, expert consensus documents state that cardiac catheterization may be indicated to confirm the echocardiographic diagnosis of pulmonary hypertension, determine disease severity, evaluate the potential contributions of shunt lesions (eg, atrial or ventricular septal defects, patent ductus arteriosus), and define the need for combination drug therapy for the treatment of pulmonary hypertension.(97) (98) **(EG 2)** Expert consensus documents recommend right heart catheterization for patients with tricuspid valve disease in order to screen for pulmonary hypertension, establish candidacy for transcatheter procedures, guide treatment plans, and provide prognostic information.(99)(100)(101) **(EG 2)**

For valvular heart disease, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Coronary angiography is indicated prior to valve surgery for evaluation of the coronary arteries in patients with suspected or known coronary artery disease or decreased left ventricular systolic function, in all male patients age 40 years or older, and in all postmenopausal female patients. It is also indicated when findings on noninvasive testing are internally inconsistent or when they are discordant with clinical findings. A specialty society guideline states that coronary angiography should be performed as part of the evaluation of patients with chronic severe secondary mitral regurgitation. Cardiac catheterization may be indicated to assess hemodynamics, coronary artery anatomy, and severity of valve disease in the setting of equivocal echocardiographic evidence regarding the severity of valvular heart disease.(103) **(EG 2)**

Inconclusive or Non-Supportive Evidence

For routine preoperative screening, evidence demonstrates a lack of net benefit; additional research is recommended. **(RG C1)** A specialty society guideline states that no benefit has been found for the use of coronary angiography for routine preoperative screening.(10) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(109); 42 CFR 422.101(110)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(111); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(112); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(113)

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Footnotes

[A] The Duke Treadmill Score incorporates exercise duration, the magnitude of ST-segment deviation, and exercise-induced angina; it identifies patients with a high probability of severe coronary artery disease (triple vessel or left main coronary artery disease) at angiography and with a higher mortality risk.(57) A low-risk score is +5 or greater, a moderate-risk score is between +4 and -10, and a high-risk score is -11 or less.(57) [A in Context Link 1]

[B] Risk factors for coronary artery disease include diabetes mellitus, hypertension, hyperlipidemia, tobacco use, family history of premature coronary artery disease, age, obesity, sedentary lifestyle, and chronic kidney disease.(62)(63) [B in Context Link 1, 2]

[C] Canadian Cardiovascular Society class I angina occurs only with strenuous, rapid, or prolonged exertion; class II angina occurs with rapid walking or climbing stairs or a hill, after meals, in the cold or wind, or with emotional stress; class III angina occurs while walking 1 to 2 level blocks; with class IV angina, a patient is unable to carry on any physical activity without discomfort, and angina symptoms may be present at rest.(104) [C in Context Link 1]

[D] The severity of valvular regurgitation is determined and reported by specific imaging parameters that vary according to the imaging modality and are evaluated in combination with physical examination findings. These imaging parameters include the visual appearance and anatomic location of the regurgitant jet, Doppler measurements on echocardiography, and measurements of regurgitant volume on all imaging modalities.(103)(107)(108) A specialty society guideline recommends correlating physical examination findings with data from a comprehensive transthoracic echocardiogram when classifying the severity of valve lesions for the purposes of evaluating patients for a possible intervention.(103) [D in Context Link 1]

Definitions

Altered mental status

- Altered mental status (ie, different from baseline), as indicated by **1 or more** of the following(1)(2)(3)(4):
 - Confusional state (eg, disorientation, difficulty following commands, deficit in attention)
 - Lethargy (eg, awake or arousable, but with drowsiness; reduced awareness of self and environment)
 - Obtundation (ie, arousable only with strong stimuli, lessened interest in environment, slowed responses to stimulation)
 - Stupor (ie, may be arousable but patient does not return to normal baseline level of awareness)
 - Coma (ie, not arousable)

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Hypotension

- Hypotension, as indicated by **1 or more** of the following:
 - Hypotension in adult patient, as indicated by **1 or more** of the following:
 - Systolic blood pressure less than 90 mm Hg[A][B](1)
 - Mean arterial pressure[C] less than 70 mm Hg[A][B]  MAP Calculator(1)(2)
 - Decrease in baseline systolic blood pressure of 30 mm Hg or more, with significant signs or symptoms due to lower blood pressure (eg, near syncope, syncope, chest pain)[A][B](1)
 - Hypotension in pediatric patient, as indicated by **1 or more** of the following:
 - Systolic blood pressure less than 110 mm Hg in child 13 to 17 years of age[A][D](3)
 - Systolic blood pressure less than 100 mm Hg in child 6 to 12 years of age[A][D](3)
 - Systolic blood pressure less than 95 mm Hg in child 3 to 5 years of age[A][D](3)
 - Systolic blood pressure less than 90 mm Hg in child 1 or 2 years of age[A][D](3)
 - Systolic blood pressure less than 80 mm Hg in infant 6 to 11 months of age[A][D](3)
 - Systolic blood pressure less than 70 mm Hg in infant 3 to 5 months of age[A][D](3)
 - Systolic blood pressure less than 65 mm Hg in infant 1 or 2 months of age[A][D](3)

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2. Puskarich MA, Jones AE. Shock. In: Walls RM, editor. Rosen's Emergency Medicine: Concepts and Clinical Practice. 10th ed. Elsevier; 2023:34-41.e1.
3. Anderson CC, Kapoor S, Mark TE. Pediatric parameters and equipment. In: Anderson CC, Kapoor S, Mark TE, editors. The Harriet Lane Handbook: A Manual for Pediatric House Officers. 23rd ed. Elsevier; 2024:i-iii.

Footnotes

- A. Criteria based upon clinician-acquired numeric values (eg, vital signs, oxygen saturation) should be used if they are accurate reflections of the patient's condition. Transitory findings (eg, abnormal only upon initial emergency department intake or only one time out of multiple readings) that rapidly improve with no or minimal treatment usually do not reflect disease severity or risk for deterioration. This does not imply that an initial or one-time reading cannot ever be applicable. The goal is to separate erroneous or incidental findings from those that truly represent the patient's clinical picture.
- B. Interpretation of blood pressure requires clinical judgment and consideration of several patient-specific factors, such as the patient's baseline blood pressure, medications, and clinical impact. For example, an elderly patient with heart failure may be prescribed medication with the intentional goal of a reduced pressure. If the patient's baseline SBP is 92 mm Hg to 96 mm Hg, absent signs or symptoms of hypotension, an emergency department SBP of 86 mm Hg should not automatically be categorized as hypotensive. This would hold for mean arterial pressure (MAP) as well. The numeric values included in this definition are provided to allow for consistency in terms of a technical definition of the term hypotension. Whether a blood pressure below the technical threshold is clinically meaningful is a matter of persistence, context, and clinical judgment.
- C. The mean arterial pressure (MAP) takes into account both SBP and DBP readings.
- D. Interpretation of blood pressure requires clinical judgment and consideration of several patient-specific factors, such as the patient's baseline blood pressure, medications, and clinical impact. The numeric values included in this definition are provided to allow for consistency in terms of a technical definition of the term hypotension. Whether a blood pressure below the technical threshold is clinically meaningful is a matter of persistence, context, and clinical judgment.

Tachycardia

- Tachycardia,[A][B] as indicated by **1 or more** of the following:
 - Heart rate greater than 100 beats per minute in adult[A][B](1)
 - Heart rate greater than 85 beats per minute in child 13 to 17 years of age[A][C](2)
 - Heart rate greater than 95 beats per minute in child 6 to 12 years of age[A][C](2)
 - Heart rate greater than 110 beats per minute in child 1 to 5 years of age[A][C](2)
 - Heart rate greater than 120 beats per minute in infant 3 to 11 months of age[A][C](2)
 - Heart rate greater than 150 beats per minute in infant 1 or 2 months of age[A][C](2)

References

1. Schriger DL. Approach to the patient with abnormal vital signs. In: Goldman L, Cooney KA, editors. Goldman-Cecil Medicine. 27th ed. Elsevier; 2024:32-35.
2. Anderson CC, Kapoor S, Mark TE. Pediatric parameters and equipment. In: Anderson CC, Kapoor S, Mark TE, editors. The Harriet Lane Handbook: A Manual for Pediatric House Officers. 23rd ed. Elsevier; 2024:i-iii.

Footnotes

- A. Criteria based upon clinician acquired numeric values (eg, vital signs, oxygen saturation) should be used if they are accurate reflections of the patient's condition. Transitory findings (eg, abnormal only upon initial emergency department intake or only one time out of multiple readings) that rapidly improve with no

or minimal treatment usually do not reflect disease severity or risk for deterioration. This does not imply that an initial or one-time reading cannot ever be applicable. The goal is to separate erroneous or incidental findings from those that truly represent the patient's clinical picture.

- B. Interpretation of heart rate requires clinical judgment and consideration of several patient-specific factors, such as the patient's baseline heart rate, medications, and clinical impact. For example, an elderly patient on a beta-blocker medication with a baseline resting heart rate of 60 beats per minute may be clinically tachycardic at a heart rate of 94 beats per minute. Likewise, a patient who is upset, in pain, or nervous in the emergency department with a heart rate of 106 beats per minute may meet the technical definition of tachycardia, but this tachycardia (absent associated findings such as chest pain or hypotension) may not be clinically important. The numeric values included in this definition are provided to allow for consistency in terms of a technical definition of the term tachycardia. Whether a heart rate above or below the technical threshold is clinically meaningful is a matter of persistence, context, and clinical judgment.
- C. Interpretation of heart rate requires clinical judgment and consideration of several patient-specific factors, such as the patient's baseline heart rate, medications, and clinical impact. A patient who is upset, in pain, or nervous in the emergency department with an elevated heart rate may meet the technical definition of tachycardia, but this tachycardia (absent associated findings such as hypotension) may not be clinically important. The numeric values included in this definition are provided to allow for consistency in terms of a technical definition of the term tachycardia. Whether a heart rate above or below the technical threshold is clinically meaningful is a matter of persistence, context, and clinical judgment.

Codes

CPT®: 0523T, 92978, 92979, 93451, 93452, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, 93462, 93505, 93563, 93564, 93565, 93566, 93567, 93568, 93569, 93571, 93572, 93573, 93574, 93575, 93584, 93585, 93586, 93587, 93588, 93593, 93594, 93595, 93596, 93597, 93598 [Hide]

HCPCS: C7516, C7517, C7518, C7519, C7520, C7521, C7522, C7523, C7524, C7525, C7526, C7527, C7528, C7529, C7552, C7553, C7557, C7562, C7568, C7570 [Hide]

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