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Clinical Appropriateness Guidelines

Cardiology

Appropriate Use Criteria: Diagnostic Coronary Angiography

Proprietary

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Table of Contents

- Clinical Appropriateness Guidelines..... 1
- Table of Contents..... 2
- Description and Application of the Guidelines 3
- General Clinical Guideline..... 4
- Diagnostic Coronary Angiography..... 6
 - Codes 6
 - General Information 6
 - Requirements 9
 - Clinical Indications 9
 - References 11
- History 13

Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. As used by Carelon, the Guidelines establish objective and evidence-based criteria for medical necessity determinations where possible. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary (i.e., in general, shown to be effective in improving health outcomes and considered the most appropriate level of service)
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Relevant citations are included in the References section attached to each Guideline. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the Carelon Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new 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 and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study

- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered.

Diagnostic Coronary Angiography

Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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93454	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation
93455	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography
93456	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization
93457	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization
93458	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed
93459	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography
93460	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed
93461	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography

General Information

Standard Anatomic Coverage

- Coronary arteries

Guideline Scope

- This guideline addresses the appropriate use of nonemergency coronary angiography. It does not pertain to coronary angiography when performed as part of an inpatient stay nor does it apply when urgent coronary angiography is performed in patients with unstable coronary syndrome (myocardial infarction and/or unstable angina pectoris).

- Diagnostic cardiac catheterization procedures that DO NOT include coronary angiography (e.g., isolated right heart catheterization, isolated left heart catheterization, combined right and left heart catheterization, aortography) are not subject to preauthorization and are therefore not addressed in this document.

Imaging Considerations

- In addition to coronary angiography, diagnostic cardiac catheterization may include any or all of the following: left heart catheterization, right heart catheterization, left ventriculography, right ventriculography, aortography and intracardiac shunt studies. Only procedures which provide clinically relevant information should be performed at the time of coronary angiography.
- Selection of the optimal diagnostic imaging study for coronary artery evaluation should be made within the context of other available modalities (which include treadmill stress test, myocardial perfusion imaging, stress echocardiography, cardiac CT, cardiac MRI, and cardiac PET), so that the resulting information facilitates patient management decisions and does not merely add a new layer of testing.
- Although the risk-benefit ratio for any procedure should dictate clinical appropriateness on a case-by-case basis, advanced age, advanced renal disease, advanced malignancy, or coagulopathy should be considered relative contraindications to coronary angiography.
- Providers who refer patients for coronary angiography and those who perform such procedures are responsible for considering safety issues. One of the most significant considerations is the requirement for intravascular iodinated contrast material, which may have an adverse effect on patients with a history of documented allergic contrast reactions or atopy, as well as on individuals with renal impairment, who are at greater risk for contrast-induced nephropathy.
- Since coronary angiography requires the use of fluoroscopy, it is critically important that every effort be made to minimize both patient and laboratory staff exposure to ionizing radiation.
- For most subgroups of patients with stable coronary artery disease (CAD), coronary revascularization procedures have not been shown to reduce mortality or incidence of myocardial infarction. Percutaneous revascularization has been shown to ameliorate angina or anginal equivalent symptoms. Therefore, in asymptomatic patients, coronary angiography with a view to percutaneous revascularization is seldom justified.
- In stable CAD patients with advanced chronic kidney disease, revascularization confers no benefit over medical management and risks of coronary angiography are higher. This is true regardless of symptom status or degree of abnormality on stress testing.
- Coronary angiography followed by revascularization (in combination with Guideline Directed Medical Therapy [GDMT]) does not improve outcomes, compared to GDMT alone, for most patients with stable CAD. Therefore, GDMT should generally be instituted prior to coronary angiography in patients with stable CAD. Exceptions to this approach include patients with left main CAD, left ventricular ejection fraction 35% or less, advanced heart failure, or revascularization within the preceding year.

Definitions

Advanced Chronic Kidney Disease: On dialysis or with Glomerular Filtration Rate < 30 ml per minute per 1.73 m²

Sustained ventricular tachycardia: Ventricular tachycardia persisting for at least 30 seconds or requiring termination due to hemodynamic instability.

New York Heart Association (NYHA) functional class: Symptom-based classification of the severity of heart failure as outlined below.

- Class I. Individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.

- Class II. Individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity (e.g., moderate physical exertion, such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.
- Class III. Individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- Class IV. Individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

Guideline-directed medical therapy (GDMT) consists of risk factor management and, in symptomatic patients, antianginal medications which improve quality of life.

- Risk factor management: All patients with stable CAD should be encouraged to adopt healthy lifestyles including tobacco cessation/avoidance, regular physical activity, maintenance of a healthy weight and adherence to a healthy diet. In addition, absent a contraindication, all stable CAD patients should be taking the following evidence-supported medications:
 - Antiplatelet agents – Aspirin and/or P2Y₁₂ receptor antagonist
 - Statin – Maximum tolerated dose of high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg). Patients intolerant of statins and/or not reaching LDL cholesterol goal on maximum tolerated statin dose should be treated with ezetimibe, a PCSK9 inhibitor, or bempedoic acid.
 - Beta blockers – In patients with a history of myocardial infarction, who have left ventricular systolic dysfunction (ejection fraction \leq 40%), or as an option for management of hypertension.
 - ACE Inhibitor or Angiotensin Receptor Blocker – In patients with left ventricular systolic dysfunction (ejection fraction \leq 40%), diabetes, chronic kidney disease, or as an option for management of hypertension
 - Antidiabetic agents – For patients who are diabetic (Hemoglobin A1c goal should be $<$ 8% in all patients although more aggressive management may be appropriate for some)
- Symptom control: Most patients with stable CAD who have symptoms should be offered anti anginal medications as an initial approach with revascularization reserved for those who have persistent unacceptable symptoms despite maximally tolerated doses.
 - Beta blockers – Unless contraindicated beta blockers are first-line therapy with dose escalation until symptoms resolve or side effects develop.
 - Calcium channel blockers and/or long acting-nitrates should be used as alternative initial therapy in symptomatic patients who have contraindication to, or intolerance of, beta blockers. They should also be prescribed when symptoms persist despite maximum tolerated doses of beta blockers.
 - Ranolazine may be prescribed either as initial therapy in symptomatic patients who have contraindication to, or intolerance of, other antianginal medication, or for those with persistent symptoms despite treatment with other medications as described above.

Recent: Within the past 90 days

Established CAD: For purposes of this guideline, patients with **any of the following** are considered to have established CAD. (Patients who do not meet this definition are considered to have suspected CAD).

- At least 70% stenosis (50% in the case of left main coronary artery) on CCTA or invasive coronary angiography
- History of unstable coronary syndrome
- History of percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG)

Suspected CAD: For the purposes of this guideline, patients who do not meet the above definition of Established CAD.

CCTA: CT coronary angiography

Acute coronary syndrome: Clinical term encompassing myocardial infarction (ST elevation and non-ST elevation) and unstable angina.

Unstable angina: Myocardial ischemia at rest or on minimal exertion in the absence of acute myocardial injury/necrosis. Since the diagnosis of unstable angina generally requires measurement of biochemical markers of myocardial injury or necrosis, and subsequent management at a setting that can provide cardiac rhythm monitoring and intravenous medications, patients undergoing elective outpatient coronary angiography for unstable angina must have had recent hospitalization for that condition.

Table 1. Classification of EKG treadmill and stress test results

Test Result	EKG treadmill test (performed <i>without</i> imaging)	SPECT MPI or Stress PET (performed <i>with</i> imaging)	Stress Echocardiography (performed <i>with</i> imaging)
Low risk	Duke treadmill score ≥ 5	< 5% ischemic myocardium	No stress-induced WMA
Intermediate risk	Duke treadmill score -10 to +4	5% to 10% ischemic myocardium	Stress-induced WMA in a single segment
High risk	ANY of the following: <ul style="list-style-type: none"> • Duke treadmill score ≤ -11 • ST segment elevation • Hypotension with exercise • Ventricular tachycardia • Prolonged ST segment depression 	ANY of the following: <ul style="list-style-type: none"> • > 10% ischemic myocardium • Stress-induced WMA in 2 or more segments • Significant stress-induced LV dysfunction • Transient ischemic LV dilation 	ANY of the following: <ul style="list-style-type: none"> • Stress-induced WMA in 2 or more segments • Significant stress-induced LV dysfunction • Transient ischemic LV dilation

Excerpted from Table 1.3 in the ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 Appropriate Use Criteria for Diagnostic Catheterization (Patel, 2012)

MPI = myocardial perfusion imaging; WMA = wall motion abnormality

Requirements

- Elective coronary angiography is generally to be considered only when a patient has undergone noninvasive evaluation.
- Coronary angiography requires conscious sedation; it should only be performed at locations where cardiac monitoring and appropriate equipment for cardiopulmonary resuscitation are readily available.
- Coronary angiography is never clinically appropriate when used as a screening test in asymptomatic individuals.

Clinical Indications

Patients with established CAD

Diagnostic coronary angiography is considered medically necessary in **ANY** of the following scenarios:

- Significant stenosis ($\geq 50\%$) in an unprotected left main coronary artery on recent CCTA
- Lesions of unclear severity in an unprotected left main coronary artery on recent CCTA
- Persistence or recurrence of unacceptable symptoms in patients with established CAD on CCTA
- **ANY** of the following findings on recent noninvasive stress testing:

- Stress-induced left ventricular dilation
- Stress-induced fall in left ventricular ejection fraction
- Increased lung/heart isotope uptake on stress imaging
- Significant fall in systolic blood pressure during exercise (> 10 mmHg)
- Stress-induced ventricular fibrillation or sustained ventricular tachycardia
- Intermediate- or high-risk findings (other than those listed above) on recent noninvasive stress testing (see [Table 1](#)) with **ANY** of the following:
 - Left main CAD is suspected and CCTA is not available or contraindicated
 - NYHA class III or IV heart failure
 - Left ventricular ejection fraction < 35%
 - Persistence or recurrence of unacceptable symptoms despite GDMT
 - CABG or PCI within the preceding year
- Low-risk findings on noninvasive stress testing (see [Table 1](#)) in patient with persistence of unacceptable ischemic equivalent symptoms despite GDMT when CCTA is not available or contraindicated
- Angina, heart failure, arrhythmia, or abnormal stress testing despite GDMT within 90 days of inpatient evaluation for acute coronary syndrome (ACS)
- Within 45 days of STEMI in a patient known to have significant non-culprit vessel(s) stenosis with a view to percutaneous revascularization of that vessel(s)

Patients with suspected CAD

Diagnostic coronary angiography is considered medically necessary in **ANY** of the following scenarios:

- Lesions of unclear severity in an unprotected left main coronary artery on recent CCTA
- Newly recognized resting LV systolic dysfunction (ejection fraction \leq 40%) when non-ischemic etiologies have been excluded in patients who are at intermediate or high risk of CAD (using ASCVD Pooled Cohort Equations)
- Persistence or recurrence of unacceptable symptoms in patients with > 50% stenosis on CCTA
- **ANY** of the following findings on recent noninvasive stress testing:
 - Stress-induced left ventricular dilation
 - Stress-induced fall in left ventricular ejection fraction
 - Increased lung/heart isotope uptake on stress imaging
 - Significant fall in systolic blood pressure during exercise (>10 mmHg)
 - Stress-induced ventricular fibrillation or sustained ventricular tachycardia
- Intermediate- or high-risk findings (other than those listed above) on recent noninvasive stress testing (see [Table 1](#)) with **ANY** of the following:
 - Left main CAD is suspected and CCTA is not available or contraindicated
 - NYHA class III or IV heart failure
 - Persistence of unacceptable symptoms despite GDMT
- Low-risk findings on noninvasive stress testing (see [Table 1](#)) in patient with persistence of unacceptable ischemic equivalent symptoms despite GDMT when CCTA is not available or contraindicated

- Equivocal or uninterpretable noninvasive stress testing in a patient with persistent symptoms when CCTA is not available or contraindicated

Patients with either suspected or established CAD

Diagnostic coronary angiography is considered medically necessary in **ANY** of the following scenarios:

- Patients resuscitated from sudden cardiac death (SCD) or with documented ventricular fibrillation or sustained ventricular tachycardia when coronary angiography has not been performed since SCD or identification of the arrhythmia
- Following cardiac transplant in a patient who has not undergone coronary angiography in the preceding 6 months
- Patients undergoing evaluation for transcatheter aortic valve replacement (TAVR) who fall into **ANY** of the following categories:
 - Men aged 41 years or older
 - Women who are postmenopausal
 - Established CAD
 - Intermediate or high risk of CAD (using ASCVD Pooled Cohort Equations)
 - Recent noninvasive testing (stress test or CCTA) suggesting CAD
- Patients undergoing evaluation for transcatheter valve replacement/repair (other than aortic valve replacement) or surgical valve replacement/repair who fall into **ANY** of the following categories:
 - Chronic severe secondary mitral regurgitation
 - Angina
 - Decreased LV systolic function
 - Established CAD
 - High risk of CAD (using ASCVD Pooled Cohort Equations)
 - Recent noninvasive testing (stress test or CCTA) suggesting CAD
- Congenital heart disease in **EITHER** of the following scenarios:
 - To exclude coexistent atheromatous CAD in patients undergoing surgical repair of congenital heart disease who have intermediate or high risk of CAD (using ASCVD Pooled Cohort Equations)
 - To evaluate congenital coronary artery anomalies when **ANY** of the following apply:
 - Diagnosis has been established using CCTA or cardiac MR, and coronary angiography will provide additional information which will change management
 - Patient has undergone CCTA or cardiac MR, and the diagnosis could not be excluded
 - Neither CCTA nor MRI is available to establish or exclude the diagnosis in a patient with suspected disease
 - CCTA and MRI have been considered, but neither study is considered to be appropriate for a patient with suspected disease

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History

Status	Review Date	Effective Date	Action
Revised	05/26/2021	03/13/2022	IMPP review. Aligned guidelines with ISCHEMIA trial such that only those with persistent unacceptable symptoms and moderate or severe stress test abnormalities can proceed to coronary angiography/revascularization. Removed indication for asymptomatic patients. Expanded criteria to include non-culprit vessels in patients following STEMI. Added criteria for use prior to TAVR. Added references.
Revised	12/03/2020	09/12/2021	IMPP review. Replaced use of SCORE risk calculator with the AHA/ACC risk calculator (ASCVD Pooled Cohort Equations). Added reference.
Revised	02/03/2020	03/14/2021	IMPP review. Added criteria to specify appropriate scenarios for evaluation of suspected congenital coronary artery anomalies.
Revised	07/11/2018	03/09/2019	IMPP review. Added the General Clinical Guideline.
Revised	03/01/2018	06/11/2018	IMPP review. Added language in preamble section to clarify application of this guideline to elective coronary angiography.
Revised	03/06/2017	01/02/2018	IMPP review. Original effective date.
Created	08/27/2015	-	Date of origin.