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Clinical Appropriateness Guidelines

Cardiovascular

Appropriate Use Criteria: Percutaneous Coronary Intervention

Proprietary

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Table of Contents

Description and Application of the Guidelines	3
General Clinical Guideline	4
Clinical Appropriateness Framework	4
Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions	4
Repeat Diagnostic Intervention	4
Repeat Therapeutic Intervention	5
Percutaneous Coronary Intervention	6
Codes	6
General Information	7
Description and Scope	7
Guideline Interpretation	7
Definitions	8
Table 1. Noninvasive Risk Stratification	10
Clinical Indications	11
PCI in patients who have not undergone CABG	11
PCI in patients who have undergone CABG	12
Other scenarios	12
Exclusions	13
Rationale	13
References	13
History	16

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. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- 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 address 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 and legal 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. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

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, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. 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 is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

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 justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

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. Requests for on-going services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

Percutaneous Coronary Intervention

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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CI VICCS. 7 (IVI	t assumes no liability for the data contained noterin or not contained noterin.			
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch			
92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)			
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch			
92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)			
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch			
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)			
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch			
92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)			
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel			
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (List separately in addition to code for primary procedure)			
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel			
92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (List separately in addition to code for primary procedure)			
92972	Percutaneous transluminal coronary lithotripsy			
92975	Thrombolysis, coronary; by intracoronary infusion, including selective coronary angiography			
C1714	Catheter, transluminal atherectomy, directional			
C1724	Catheter, transluminal atherectomy, rotational			
C1725	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)			
C1753	Catheter, intravascular ultrasound			
C1760	Closure device, vascular (implantable/insertable)			
C1761	Catheter, transluminal intravascular lithotripsy, coronary			
C1769	Guide wire			

C1874	Stent, coated/covered, with delivery system			
C1875	Stent, coated/covered, without delivery system			
C1876	Stent, non-coated/non-covered, with delivery system			
C1877	Stent, non-coated/non-covered, without delivery system			
C1885	Catheter, transluminal angioplasty, laser			
C1887	Catheter, guiding (may include infusion/perfusion capability)			
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch			
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)			
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch			
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)			
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel			
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)			
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel			
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)			

General Information

Description and Scope

Emergency percutaneous coronary intervention (PCI) is used for management of acute coronary syndromes (ST segment elevation myocardial infarction, non-ST elevation myocardial infarction, or unstable angina pectoris). PCI is also used electively for the management of stable ischemic heart disease (SIHD). This guideline addresses the clinical appropriateness of elective PCI for management of SIHD.

Percutaneous transluminal coronary lithotripsy is also addressed in this guideline while evidence supporting its use is evolving. Thus far, published clinical studies have focused on feasibility and safety but have not adequately addressed long-term clinical outcomes. Published studies are also limited by lack of a randomized control group, focus on angiographic rather than clinical outcomes, and short duration of follow-up.

Guideline Interpretation

PCI may include any or all of the following components: balloon angioplasty, coronary stent placement, or coronary atherectomy. Specific procedure selection is at the discretion of the operating physician. The term PCI applies to intervention on either native coronary arteries or coronary bypass grafts (both arterial and venous).

Determination of the appropriateness of PCI requires knowledge of the results of diagnostic coronary angiography. Each of the three epicardial coronary arteries (Left Anterior Descending, Right Coronary Artery and Circumflex Coronary Artery) (and their branches) is considered to be a single vascular territory. Thus, significant

stenosis of the left anterior descending coronary artery and the diagonal branch thereof constitutes single vessel disease while significant stenosis of the left anterior descending coronary artery and the right coronary artery would be considered two-vessel disease.

Frequently, PCI is performed at the same sitting as diagnostic coronary angiography. Although there is sometimes clinical justification to separate the two procedures, separate procedures based on facility operational requirements should be avoided wherever possible.

In some clinical situations, coronary artery bypass grafting (CABG) may be considered as an alternative to PCI as a method of revascularization. Although the literature addresses the relative indications for PCI versus CABG for cohorts of patients, it is recognized that clinical characteristics and choices of individual patients must also be considered.

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 large randomized controlled studies, coronary angiography followed by revascularization (in combination with Guideline Directed Medical Therapy [GDMT]) did 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.

Stable CAD patients with advanced chronic kidney disease have increased risks associated with revascularization. Furthermore, with the possible exception of those with left main CAD, this group has not been shown to benefit from revascularization. This is true regardless of symptom status or degree of abnormality on stress testing.

For patients who have sustained an ST elevation myocardial infarction (STEMI) within the preceding 45 days, it is reasonable to electively perform percutaneous revascularization of non-culprit angiographically significant coronary stenoses. Whether the non-culprit lesion is addressed during or subsequent to the STEMI, hospitalization does not affect the beneficial outcomes.

Although the risk-benefit ratio for any procedure should dictate clinical appropriateness on a case-by-case basis, advanced age, advanced malignancy, or coagulopathy should be considered relative contraindications to PCI.

Providers who refer patients for PCI and those who perform such procedures are responsible for considering safety issues. Particular attention should be given to 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 PCI requires the use of fluoroscopy, it is critically important that every effort be made to minimize exposure of the patient and the laboratory staff to ionizing radiation.

In clinical scenarios where appropriateness of PCI is based on findings at noninvasive testing, only testing performed since the most recent revascularization procedure (PCI or CABG) should be considered.

Definitions

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

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 who are intolerant of statins or unable to reach their LDL cholesterol goal on the 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 ≤ 40%), or as an option for management of hypertension.
 - ACE Inhibitor or Angiotensin Receptor Blocker In patients with left ventricular systolic dysfunction (ejection fraction ≤ 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 antianginal 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 a 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.

Significant coronary artery stenosis is defined as any of the following findings on invasive coronary angiography or CCTA

- Left main coronary stenosis ≥ 50%
- Non left main epicardial coronary stenosis ≥ 90%
- 40%-89% stenosis in any epicardial coronary artery with either of the following
 - o Fractional Flow Reserve (FFR) or FFR-CT ≤ 0.8
 - Instantaneous wave-free ratio (iFR) ≤ 0.89

Fractional Flow Reserve (FFR): Ratio of the pressure distal to a stenosis relative to the pressure proximal to the stenosis. FFR may be calculated invasively during hyperemia induced by a vasodilating agent (typically adenosine) or noninvasively from CCTA.

Instantaneous wave-free ratio (iFR): A measurement of the resting pressure gradient across a coronary stenosis during the portion of diastole when microvascular resistance is low and stable.

CCTA: CT coronary angiography

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.

Revascularization: Coronary artery bypass grafting or percutaneous coronary intervention

Low complexity coronary disease: Focal stenosis and/or SYNTAX score ≤ 22

High complexity coronary disease: Diffuse stenosis(es) and/or SYNTAX score > 22

SYNTAX score: An approach to quantifying the complexity of triple vessel disease (with or without left main involvement) to facilitate treatment decision-making

Table 1. Noninvasive Risk Stratification

High risk (> 3% annual death or myocardial infarction)

- 1. Severe resting LV dysfunction (LVEF < 35%) not readily explained by noncoronary causes
- 2. Resting perfusion abnormalities ≥10% of the myocardium in patients without prior history or evidence of myocardial infarction
- 3. 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/ventricular fibrillation
- 4. Severe stress-induced LV dysfunction (peak exercise LVEF < 45% or drop in LVEF with stress ≥ 10%)
- 5. Stress-induced perfusion abnormalities encumbering ≥ 10% myocardium or stress segmental scores indicating multiple vascular territories with abnormalities
- 6. Stress-induced LV dilation
- 7. Inducible wall motion abnormality (involving > 2 segments or 2 coronary beds)
- 8. Wall motion abnormality developing at low dose of dobutamine (≤ 10 mg/kg/min) or at a low heart rate (< 120 beats/min)
- 9. CAC score > 400 Agatston units
- 10. Multivessel obstructive CAD (≥ 70% stenosis) or left main stenosis (≥ 50% stenosis) on CCTA

Intermediate risk (1% to 3% annual death or myocardial infarction)

- 1. Mild/moderate resting LV dysfunction (LVEF 35% to 49%) not readily explained by noncoronary causes
- 2. Resting perfusion abnormalities in 5% to 9.9% of the myocardium in patients without a history or prior evidence of myocardial infarction
- 3. ≥ 1 mm of ST-segment depression occurring with exertional symptoms
- 4. Stress-induced perfusion abnormalities encumbering 5% to 9.9% of the myocardium or stress segmental scores (in multiple segments) indicating 1 vascular territory with abnormalities but without LV dilation
- 5. Small wall motion abnormality involving 1 to 2 segments and only 1 coronary bed

- 6. CAC score 100 to 399 Agatston units
- 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 myocardial infarction)

- 1. 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 encumbering < 5% of the myocardium*
- 3. Normal stress or no change of limited resting wall motion abnormalities during stress
- 4. CAC score < 100 Agatston units
- 5. No coronary stenosis > 50% on CCTA

CAC indicates coronary artery calcium; CAD, coronary artery disease; CCTA, coronary computed tomography angiography; LV, left ventricular; LVEF, left ventricular ejection fraction.

Reproduced from Fihn SD, et al. J Am Coll Cardiol. 2012.

Clinical Indications

The following indications for elective PCI are accompanied by pretest considerations as well as supporting clinical data and prerequisite information. For noninvasive risk stratification, refer to **Table 1**.

PCI in patients who have not undergone CABG

Non-Left Main PCI

PCI of one or two (2) vascular territories (at a single sitting) is appropriate when there is significant stenosis of each vessel treated and ANY of the following scenarios (A-G) apply:

- A. Abnormal stress testing with **ANY** of the following:
 - Persistence or recurrence of unacceptable ischemic symptoms despite optimal medical therapy
 - NYHA class III or IV CHF
 - Left ventricular ejection fraction ≤ 35%
 - PCI within the past year
- B. Newly recognized left ventricular systolic dysfunction (ejection fraction ≤ 40%) when ischemia is thought to be the cause of LV dysfunction.
- C. ST elevation myocardial infarction (STEMI) within the preceding 45 days and residual non-culprit stenosis which was not addressed during the STEMI admission.
- D. Anginal equivalent symptoms, heart failure, sustained ventricular arrhythmia, or abnormal stress test within 90 days of inpatient management acute coronary syndrome when PCI was not performed at the time of the acute coronary syndrome.
- E. Abnormal CCTA with ANY of the following:
 - Persistence or recurrence of unacceptable ischemic symptoms despite optimal medical therapy
 - NYHA class III or IV CHF
 - Left ventricular ejection fraction ≤ 35%

^{*}Although the published data are limited, patients with these findings will probably not be at low risk in the presence of either a high-risk treadmill score or severe resting LV dysfunction (LVEF < 35%).

- PCI within the past year
- F. Recently resuscitated from sudden cardiac death or with documented ventricular fibrillation or sustained ventricular tachycardia
- G. Prior cardiac transplant

Note: Consideration should be given to coronary artery bypass grafting (CABG) as an alternative to PCI in patients with two (2) vessel disease involving the proximal left anterior descending coronary artery. Outcomes with CABG in this scenario may be better and particularly so in diabetic patients or those with significant left ventricular systolic dysfunction.

PCI of three (3) vascular territories (at a single sitting) is appropriate in the scenarios (A-G) above when there is significant stenosis of each vessel treated and ANY of the following apply:

- Low complexity coronary disease
- High complexity coronary disease with documentation of the patient's refusal to undergo CABG
- High complexity coronary disease and comorbid conditions such that CABG is contraindicated

Left Main PCI

PCI of an unprotected left main coronary artery is appropriate when there is significant stenosis and EITHER of the following applies:

- There is documentation of the patient's refusal to undergo CABG
- CABG is contraindicated due to comorbid conditions

PCI in patients who have undergone CABG

Patients who have undergone CABG within the preceding year and have ALL of the following:

- Ischemic symptoms (including symptomatic ventricular tachycardia)
- Stenosis (70% or greater) in a native vessel(s) or bypass graft(s)
- Intermediate or high-risk findings on noninvasive stress testing (<u>Table 1</u>)*

*If noninvasive stress testing has not been performed or is indeterminate, $FFR \le 0.8$ or $iFR \le 0.89$ will substitute for this requirement.

Patients who have undergone CABG more than one (1) year previously and have ALL of the following:

- Persistence or recurrence of unacceptable ischemic symptoms despite optimal medical therapy or symptomatic ventricular tachycardia
- Stenosis (70% or greater) in a native vessel(s) or bypass graft(s)
- Abnormal (low, intermediate, or high-risk findings) on noninvasive stress testing*

*If noninvasive stress testing has not been performed or is indeterminate, $FFR \le 0.8$ or $iFR \le 0.89$ will substitute for this requirement.

Other scenarios

Scheduled to undergo percutaneous valvular procedures (e.g., TAVR/TAVI or mitral valve repair) when ANY of the following apply:

Left main CAD (except for complex bifurcation disease)

- Non-complex triple vessel disease (e.g., SYNTAX score < 33)
- Complex triple vessel disease in a patient who is not a candidate for CABG
- One (1) or two (2) vessel proximal CAD

Scheduled to undergo renal transplantation when ANY of the following apply and CAD complexity is low:

- Persistent symptoms despite maximal antianginal therapy
- Persistent symptoms despite any antianginal therapy in non-diabetic patients with intermediate or highrisk findings on noninvasive stress testing
- Ischemic symptoms in non-diabetic patients who are not taking any antianginal therapy and have left main disease, triple vessel disease, or proximal LAD disease, with intermediate or high-risk findings on noninvasive stress testing

Exclusions

Percutaneous transluminal coronary lithotripsy

Percutaneous transluminal coronary lithotripsy is considered **not medically necessary** in all scenarios.

Rationale

The definition of significant anatomic stenosis (50% or greater in the left main coronary artery or 70% or greater in other coronary vessels) in this guideline is based on that used by professional society guidelines.²⁹

In patients with left main CAD, evidence from 3 randomized controlled trials (SYNTAX, Le MANS, and PRECOMBAT) suggests that clinical outcomes at 1- to 2-year follow-up are similar when comparing PCI and CABG but repeat revascularization rates are higher after PCI than after CABG. In diabetic patients with multivessel CAD who have failed GDMT, there is significant evidence, including a meta-analysis of 8 trials that includes the FREEDOM trial, which shows a lower all-cause mortality rate with CABG than with PCI at 5 years or at longest follow-up. Therefore, professional society guidelines generally recommend the use of CABG rather than PCI in this scenario. ¹⁰ Additionally, professional society guidelines recommend CABG over PCI in patients with complex 3-vessel CAD who are good candidates for CABG. ¹¹

In patients with chronic stable CAD, evidence from multiple meta-analyses as well as the 5179-patient ISCHEMIA trial has shown that, while anginal symptoms are improved by the combination of PCI and optimal medical therapy (OMT), the routine addition of PCI does not result in improved mortality or myocardial infarction rates compared to OMT alone. 13,34,35,36

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History

Status	Review Date	Effective Date	Action
Revised	01/23/2024	10/20/2024	Independent Multispecialty Physician Panel (IMPP) review. Added exclusion for percutaneous transluminal coronary lithotripsy. Added CPT code 92972.
Reaffirmed/ Updated	07/18/2023, 01/23/2024	Unchanged	IMPP review. Guidelines reaffirmed. Added required language per new Medicare regulations. Expanded guideline rationale. Added references.
Reaffirmed	07/18/2023	Unchanged	IMPP review. Guidelines reaffirmed.
Revised	02/03/2022	06/18/2023	IMPP review. Clarified noninvasive testing refers to stress testing.
Updated	-	04/01/2023	Added CPT codes 92975, C1714, C1724, C1725, C1753, C1760, C1761, C1769, C1874, C1875, C1876, C1877, C1885, C1887. Updated references.
Revised	05/26/2021	03/13/2022	Independent Multispecialty Physician Panel (IMPP) review. Revised criteria such that, for some cohorts, only those patients with persistent unacceptable symptoms and moderate/severe stress test abnormalities can proceed to revascularization. For non-left main PCI: expanded use to non-culprit vessels in patients following STEMI, restricted use to those with moderate or severe stress test abnormalities who have failed medical therapy. Left main PCI limited to situations where CABG is contraindicated or refused. Include consideration of iFR. Added references.
Updated	-	06/13/2021	Added HCPCS codes C9600, C9601, C9602, C9603, C9604, C9605, C9607, C9608.
Reaffirmed	02/03/2020	Unchanged	IMPP review. Guideline reaffirmed.
Revised	07/11/2018	03/09/2019	IMPP review. Added the General Clinical Guideline.
Revised	03/01/2018	06/11/2018	IMPP review. Added clarification of inappropriateness of PCI in asymptomatic patients.
Revised	09/07/2017	01/02/2018	IMPP review. Incorporated American College of Cardiology appropriate use for PCI in stable coronary artery disease. Original effective date.
Created	08/27/2015	-	Date of origin.