

Clinical Appropriateness Guidelines: Percutaneous Coronary Intervention

Appropriate Use Criteria

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Proprietary

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Description and Application of the Guidelines



AIM's Clinical Appropriateness Guidelines (hereinafter "AIM's 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 AIM, the Guidelines establish objective and evidence-based, where possible, criteria for medical necessity determinations. In the process, multiple functions are accomplished:

- 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 advocate for patient safety concerns
- To enhance the quality of healthcare
- To promote the most efficient and cost-effective use of services

AIM's 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. AIM reviews all of its Guidelines at least annually.

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

AIM 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 AIM 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. If requested by a health plan, AIM will review requests based on health plan medical policy/guidelines in lieu of AIM's Guidelines.

The Guidelines may also be used by the health plan or by AIM 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.

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CPT Codes

- 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)

Scope of this Guideline

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 for the management of stable ischemic heart disease (SIHD) is considered to be elective and is the focus of this document.

Guideline Interpretation

This guideline does not supersede the enrollee's health plan medical policy specific to PCI.

PCI may include any or all of the following: 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 both native coronary arteries and coronary bypass grafts (both arterial and venous). Determination of the appropriateness of PCI requires knowledge of the results of diagnostic coronary arteriography. In determination of the degree of angiographic disease, this guideline observes the following definition of significant coronary stenosis: $\geq 50\%$ left main stenosis, $\geq 70\%$ non-left main stenosis, or 40%-69% stenosis of an epicardial vessel with fractional flow reserve (FFR) ≤ 0.8 (measured at angiography).

Frequently, PCI is performed at the same sitting as diagnostic coronary arteriography. 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 populations of patients, it is recognized that clinical characteristics and choices of individual patients must also be considered.

Elective PCI has not been shown to be superior to optimal medical therapy for patients with stable angina pectoris. Therefore every effort should be made to optimize medical therapy before consideration of PCI.

Currently, evidence supporting use of PCI in asymptomatic patients with stable CAD is lacking. Therefore, PCI is generally reserved for symptomatic patients because, while PCI has been shown to reduce symptoms, reduction in incidence of myocardial infarction or mortality has not been demonstrated.

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 PCI.

Providers who refer patients for PCI and those who perform such procedures are responsible for considering safety issues. In particular, 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.

References to Fractional Flow Reserve (FFR) in this document should be interpreted as invasively measured FFR.

It is assumed that all patients with SIHD will be treated with secondary prevention therapies (antihypertensives, lipid lowering agents, antidiabetic agents, antiplatelet agents, etc.) where indicated. In addition, patients with symptomatic SIHD should receive antianginal medications (e.g. beta blockers, calcium channel blockers, long-acting nitrate preparations, ranolazine). For the purposes of this guideline, a patient is considered to be taking an antianginal agent if (s)he (a) is currently taking the medication at the maximally tolerated dose, (b) is intolerant of the medication or (c) has a contraindication to that class of medications.

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.

Table 1: Noninvasive Risk Stratification*

<p>High risk (>3% annual death or MI)</p> <ol style="list-style-type: none">1. Severe resting LV dysfunction (LVEF <35%) not readily explained by noncoronary causes2. Resting perfusion abnormalities > or =10% of the myocardium in patients without prior history or evidence of MI3. Stress ECG findings including > or =2 mm of ST-segment depression at low workload or persisting into recovery, exercise-induced ST-segment elevation, or exercise-induced VT/VF4. Severe stress-induced LV dysfunction (peak exercise LVEF <45% or drop in LVEF with stress > or =10%)5. Stress-induced perfusion abnormalities encumbering > or =10% myocardium or stress segmental scores indicating multiple vascular territories with abnormalities6. Stress-induced LV dilation7. Inducible wall motion abnormality (involving >2 segments or 2 coronary beds)8. Wall motion abnormality developing at low dose of dobutamine (< or =10 mg/kg/min) or at a low heart rate (<120 beats/min)9. CAC score >400 Agatston units10. Multivessel obstructive CAD (> or =70% stenosis) or left main stenosis (> or =50% stenosis) on CCTA <p>Intermediate risk (1% to 3% annual death or MI)</p> <ol style="list-style-type: none">1. Mild/moderate resting LV dysfunction (LVEF 35% to 49%) not readily explained by noncoronary causes2. Resting perfusion abnormalities in 5% to 9.9% of the myocardium in patients without a history or prior evidence of MI3. > or =1 mm of ST-segment depression occurring with exertional symptoms4. 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 dilation5. Small wall motion abnormality involving 1 to 2 segments and only 1 coronary bed6. CAC score 100 to 399 Agatston units7. One vessel CAD with > or =70% stenosis or moderate CAD stenosis (50% to 69% stenosis) in > or =2 arteries on CCTA <p>Low risk (<1% annual death or MI)</p> <ol style="list-style-type: none">1. Low-risk treadmill score (score > or =5) or no new ST segment changes or exercise-induced chest pain symptoms; when achieving maximal levels of exercise2. 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 stress4. CAC score <100 Agatston units5. No coronary stenosis >50% on CCTA
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*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%).

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

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

Indications for PCI in patients who have not undergone CABG

The following indications for elective PCI are accompanied by pre-test considerations as well as supporting clinical data and prerequisite information.

Patients with one vessel coronary artery disease

Symptomatic patients who are receiving only one (1) antianginal medication and have

- Proximal involvement;* **AND**
- Intermediate or high-risk findings on noninvasive testing

* Proximal involvement refers to involvement of the proximal LAD or of a dominant circumflex vessel.

Symptomatic patients who are receiving maximal antianginal medical therapy and have

- Abnormal noninvasive testing; **OR**
- No noninvasive testing since symptom onset and FFR ≤ 0.8 ; **OR**
- Inconclusive noninvasive testing since symptom onset and FFR ≤ 0.8

Patients with two vessel coronary artery disease

Symptomatic patients who are receiving only one (1) antianginal medication and have

- Intermediate or high-risk findings on noninvasive testing; **OR**
- No noninvasive testing since symptom onset and FFR ≤ 0.8 ; **OR**
- Inconclusive noninvasive testing since symptom onset and FFR ≤ 0.8

Symptomatic non-diabetic patients who are receiving no antianginal medication and have

- Proximal involvement #; **AND**
- Intermediate or high-risk findings on noninvasive testing

Proximal involvement refers to involvement of the proximal LAD.

Symptomatic patients who are receiving maximal antianginal medical therapy and have

- Abnormal noninvasive testing; **OR**
- No noninvasive testing since symptom onset and FFR ≤ 0.8 ; **OR**
- Inconclusive noninvasive testing since symptom onset and FFR ≤ 0.8

Patients with three vessel coronary artery disease

Symptomatic patients who are receiving maximal antianginal medical therapy and have

- Low disease complexity (e.g. focal stenosis, SYNTAX score ≤ 22)

Symptomatic patients who are receiving only one (1) antianginal medication and have

- Low disease complexity (e.g. focal stenosis, SYNTAX score ≤ 22); **AND**
- Intermediate or high-risk findings on noninvasive testing

Symptomatic non-diabetic patients who are receiving no antianginal medication and have

- Low disease complexity (e.g. focal stenosis, SYNTAX score ≤ 22); **AND**
- Intermediate or high-risk findings on noninvasive testing

Patients with left main coronary artery disease

Patients who are taking any antianginal therapy and who meet all of the following criteria

- Ischemic symptoms
- Disease does not involve the LM bifurcation
- There is no significant CAD in other coronary arteries or (if other disease is present) SYNTAX score is $<$ or $=$ 22

Patients who are not taking any antianginal therapy and who meet all of the following criteria

- Ischemic symptoms
- Disease does not involve the LM bifurcation
- There is no significant CAD in other coronary arteries

Indications for PCI in patients who have undergone CABG

Patients with a patent internal mammary artery (IMA) graft to the left anterior descending (LAD) coronary artery who are receiving only one (1) antianginal medication and meet all of the following criteria

- Ischemic symptoms
- Stenosis(es) in a native vessel(s) or bypass graft(s) supplying one (1) or two (2) vascular territories (other than the LAD)
- Intermediate or high-risk findings on noninvasive testing*

* If noninvasive testing has not been performed or is indeterminate, $FFR < \text{or} = 0.8$ will substitute for this requirement.

Patients with a patent internal mammary artery (IMA) graft to the left anterior descending (LAD) coronary artery who are receiving maximal antianginal therapy and who meet all of the following criteria

- Ischemic symptoms
- Abnormal (low, intermediate or high-risk findings) on noninvasive testing*
- Stenosis(es) in a native vessel(s) or bypass graft(s) supplying one (1) or two (2) vascular territories (other than the LAD)

* If noninvasive testing has not been performed or is indeterminate, $FFR < \text{or} = 0.8$ will substitute for this requirement.

Patients with a non-patent internal mammary artery (IMA) graft to the left anterior descending (LAD) coronary artery who are not taking any antianginal therapy, have intermediate or high-risk findings on noninvasive testing* and meet either of the following criteria

- Have ischemic symptoms and stenosis(es) in a native vessel(s) or bypass graft(s) supplying two (2) or three (3) vascular territories (including the LAD)
- Have no ischemic symptoms and stenosis(es) in a native vessel(s) or bypass graft(s) supplying three (3) vascular territories (including the LAD)

* If noninvasive testing has not been performed or is indeterminate, $FFR < \text{or} = 0.8$ will substitute for this requirement.

Symptomatic patients with a non-patent internal mammary artery (IMA) graft to the left anterior descending (LAD) coronary artery who are receiving only one (1) antianginal medication and meet one of the following criteria

- Stenosis(es) in a native vessel(s) or bypass graft(s) supplying only the LAD territory and intermediate or high-risk findings on noninvasive testing*
- Stenosis(es) in a native vessel(s) or bypass graft(s) supplying two (2) vascular territories (including the LAD) and abnormal (low, intermediate or high-risk findings) on noninvasive testing*
- Stenosis(es) in a native vessel(s) or bypass graft(s) supplying three (3) vascular territories (including the LAD) and intermediate or high-risk findings on noninvasive testing*

* If noninvasive testing has not been performed or is indeterminate, $FFR < \text{or} = 0.8$ will substitute for this requirement.

Patients with a non-patent internal mammary artery (IMA) graft to the left anterior descending (LAD) coronary artery who are receiving maximal antianginal therapy and who meet all of the following criteria

- Ischemic symptoms
- Abnormal (low, intermediate or high-risk findings) on noninvasive testing*

* If noninvasive testing has not been performed or is indeterminate, $FFR < \text{or} = 0.8$ will substitute for this requirement.

Other scenarios

Scheduled to undergo percutaneous valvular procedures (e.g. TAVR/TAVI or mitral repair) when any of the following applies

- Left main or triple vessel CAD
- One (1) or two (2) vessel CAD and intermediate or high-risk findings on noninvasive testing
- One (1) or two (2) vessel CAD with proximal LAD involvement, low-risk findings on noninvasive testing and ischemic symptoms despite any antianginal therapy
- One (1) or two (2) vessel CAD without proximal LAD involvement, low-risk findings on noninvasive testing and ischemic symptoms despite maximal antianginal therapy

Scheduled to undergo renal transplantation when any of the following applies and SYNTAX score is $< \text{or} = 22$

- Persistent symptoms despite maximal antianginal therapy
- Persistent symptoms despite any antianginal therapy in non-diabetic patients with intermediate or high-risk findings on noninvasive 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 testing

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