

Final Comments and Response

LCD Title

Percutaneous Coronary Interventions

LCD Database ID Number

L 34139

We would like to thank those who suggested changes to the DRAFT Percutaneous Coronary Interventions LCD. We received six comments which are below.

Comment

A comment was received pointing an error under Indications. The proposed DRAFT LCD states, "Intracoronary ultrasound and doppler function flow reserve studies are not required.

Response

The correction was made to correct the phrase functional flow reserve studies to fractional flow reserve studies.

Comment

A comment was received which recommended Intracoronary ultrasound (IVUS) and Doppler fractional flow reserve (FFR) studies are required for most PCI. Except in ACS or obvious severe stenosis, the use of IVUS or FFR is critical for deciding whether PCI is indicated. As shown in the FAME 2 study, <http://www.nejm.org/doi/full/10.1056/NEJMoa1205361>, the use of FFR can avoid many unnecessary stents. A reference was submitted from [fiercehealthcare](http://www.fiercehealthcare.com): "Stenting belongs to one of the bleakest chapters in the history of Western medicine." Nortin Hadler, a Professor of Medicine at the University of North Carolina at Chapel Hill, told Bloomberg, Cardiologists, he said, "continue to conduct these procedures because the interventional cardiology industry has a cash flow comparable to the GDP [gross domestic product] of many countries" and doesn't want to lose it.

Response

The LCD will be adjusted to say that FFR and IVUS is possibly indicated with multivessel CAD with appropriate documentation of medical reasonableness and medical necessity.

Comment

A comment was received addressing Ad hoc PCI should be discouraged. When a patient undergoes diagnostic catheterization, it is impossible for the patient to give proper informed consent for PCI when it is not known how many arteries will require stenting, where those stents will be placed and what options for treatment other than PCI exist based on the location and severity of the stenosis. Ad hoc PCI promotes inappropriate placement of stents, committing the patient to expensive and dangerous dual platelet therapy when optimal medical therapy with all generic medications may be equally efficacious and certainly less dangerous. References were submitted from [Putting Ad Hoc PCI on Pause](http://www.puttingadhocpci.com), Brahmajee K. Nallamothu, MD, MPH; Harlan M. Krumholz, MD, SM *JAMA*. 2010;304(18):2059-2060 and <http://jama.jamanetwork.com/article.aspx?articleid=186856>.

Response

The LCD speaks as to when cardiac catheterization is indicated and covered as medically reasonable and necessary. It does not require ad hoc PCI.

Comment

A comment was received regarding the CMS proposed guidelines of overnight stay to ad hoc PCI. While this is feasible when patient presents early to the catheterization lab, it is extremely difficult when performing PCI late and discharging patients six hours after femoral approach. This probably will lead to overuse of closure devices in an attempt to decrease ambulation time, leading to extra expenses without necessarily decreasing vascular complications. This also may force hospitals to discharge outpatients and acute patients, before stable in order to expedite discharge time. Finally, while it's rare, acute stent thrombosis is better discovered in house rather after patients leave the hospital.

Response

The language about inpatient and observation admission was clarified. The intent was to remind physicians that all PCI patients do not require inpatient admission after PCI and in fact some PCI patients can be discharged same day. It is required to submit written documentation to satisfy requirements supporting observation and inpatient admission after PCI.

Comment

A comment was received which requested incorporation of the recommendations from the Society for Cardiovascular Angiography and Interventions in their Consensus Statement on Ad Hoc Percutaneous Coronary Intervention available at <http://onlinelibrary.wiley.com/doi/10.1002/ccd.24701/pdf> and discourage the performance of ad hoc PCI. It was suggested to look at the data on PCI. As summarized in a meta analysis, there is no benefit to PCI for stable coronary artery disease. Two references were cited: <http://www.ncbi.nlm.nih.gov/pubmed/22371919> and <http://www.thennt.com/nnt/coronary-stenting-for-non-acute-coronary-disease-compared-to-medical-therapy/>.

Response

First paragraph addressed above. A statement will be added that there is no benefit to PCI for stable CAD.

Comment

There was a specific request on the following revision to the DRAFT policy.

Indications for Intracoronary ultrasound and Doppler fractional flow reserve studies

Intracoronary ultrasound (IVUS) may be separately covered when needed to assess the extent of coronary stenosis if equivocal on angiography, or when needed to assess the patency and integrity of a coronary artery during percutaneous coronary intervention (PCI). Intravascular doppler velocity and/or pressure-derived coronary fractional flow reserve (FFR) measurement may be performed to assess the degree of stenosis within a vessel if equivocal on angiography or the patency of a coronary artery during PCI. In select patients, both IVUS and FFR may be considered medically necessary to assess the same coronary artery and/or stenosis. Written documentation in the form of a procedure note is required to support medical necessity. References submitted included supporting clinical evidence (Practice Guideline – 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention; and Contemporary Reviews in Cardiovascular Medicine – Paradigm Shift to Functional Angioplasty) indicates IVUS may be separately covered during a PCI, and that both the FFR and IVUS may be considered medically necessary in select patients.

Response:

IVUS and FFR could be covered during PCI if there is adequate documentation in the medical record to support that both are medically reasonable and necessary.