Recommendation:

Rescind the current instruction (35-74, CIM) which excludes coverage of this service, replacing it with an instruction providing for coverage of this procedure when used to treat patients with severe angina, which has been refractory to medical therapy. All other uses remain non-covered at this time.

Basis for Recommendation:

NOTE: Although similar devices have been cleared for marketing by the FDA under 510(k) for other uses, the requestor, Vasomedical, Inc., asked that coverage, if granted, be restricted to the use studied in their clinical trial.

We have reviewed the material submitted by Vasomedical (the manufacturer of the device used in this procedure), consisting of the results of a multi-center clinical trial, which has been accepted for publication in a recognized medical journal. The clinical trial indicated that, for patients with severe angina refractory to medical therapy, this device provided medically effective treatment, with results lasting well beyond the period of therapy.

The study indicated that a 35-hour course of this therapy resulted in increased time until onset of ischemia and a reduction in the number and severity of anginal episodes. Evidence was presented that this effect lasted well beyond the immediate post-treatment phase, with patients symptom-free for several months to two years.

Specifications for Coverage:

The use of this device would be covered for patients with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass because: (1) their condition is inoperable, or at high risk of operative complications or post-operative failure; (2) their coronary anatomy is not readily amenable to such procedures; or (3) they have co-morbid states which create excessive risk.

Next Action:

If approved, replace current instruction (CIM 35-74), with draft instruction (copy attached) setting forth new coverage.

Approval/disapproval:

Approved: _____ Date: _____

Disapproved: _____ Date: _____

Comments: _____
_____
_____

[1] This decision memorandum represents only the first step towards making coverage of this service effective. A manual instruction must be prepared and approved, and the necessary billing and claims processing instructions must be prepared. In addition, changes must be made to bill processing systems in order to allow payment to be made for this service. Consequently, the effective date of service will not be known until the manual instruction has completed the clearance process and been assigned an effective date.