MVP/Preferred Care BENEFIT INTERPRETATION MANUAL

Cardiac Revascularization External Enhanced Couterpulsation,
Intravascular Brachytherapy,
Transmyocardial Laser Revascularization,
Drug Eluting Stents

Type of Policy

Medical

Codes

33140, 33141, 33510 – 33545, G0166, 77262, 77280, 77285, 77300, 77326, 77327, 77470, 77781-83, 92973, 92974, 92975, 92978-92984, 92995, 92996, 93508, G0290, G0291

Evidence Basis for Policy

Some Proven Benefit. This rating indicates that there are reasonably good data to support its use in the cited application(s). Further research is required to clarify clinical indications, contraindications, dosage/duration, comparison with alternative technologies, and/or impact on clinical outcomes.

Description

Catheter-based Intracoronary Brachytherapy has been approved by the FDA as a technique to reduce restenosis following transluminal intracoronary angioplasty (PTCA), primarily in those procedures with a stenosis occurring at the site of a prior stent placement (i.e., "in-stent restenosis"). The FDA has approved a number of intracoronary brachytherapy devices. This approval, however, limits the use of these devices to the treatment of in-stent restenosis in native coronary arteries and vein grafts. Intra-vascular requires the expertise of a multidisciplinary team that includes an in-plan interventional cardiologist, an in-plan radiation oncologist, and an in-plan radiation physicist.

Enhanced External Counterpulsation (EECP) is a non-invasive outpatient procedure intended to relieve angina pectoris by improving perfusion of areas of the heart deprived of adequate blood supply. Members receive external counterpulsation for one or two 60-minute treatment sessions each day (usually five days per week) for a total of 35 hours. The intended purpose of external pulsation is to increase the heart's oxygen supply while decreasing its oxygen demand. Treatment should be completed within two months of initiation of therapy.

Transmyocardial Laser Revascularization (TMLR) is a surgical technique which employs a laser to bore holes through the myocardium in an attempt to restore perfusion to areas of the heart not being adequately perfused by diseased or clogged coronaries for palliation of intractable angina.

Angioplasty plus stent implantation is a common treatment for angina. Angioplasty opens the partially blocked artery and the implanted stent keeps it open. Twenty percent of treated patients have growth of tissue within the stent causing the stent to re-block the artery. Individuals with co-morbid conditions, such as diabetes, have a higher risk of in-stent restenosis. Drug eluting stents after implantation allow a slow release of drug over a period of 15-45 days that prevents proliferation of tissue within the stent and prevents in-stent restenosis.

Indications/Criteria

Documentation of the clinical severity of the member's coronary artery disease must be submitted upon request, including but not limited to:

- clinical history of heart disease;
- medical therapies attempted and therapeutic results of such therapies;
- PTCA and/or drug eluting stents procedure indication/contraindications and clinical pertinent documentation;
- exercise testing results;
- imaging study results; and
- general medical condition and life expectancy.

In the case of EECP, the medical record must document the member's inability to undergo more traditional revascularization techniques (CABG, PTCA). External cardiac assist, EECG, pulse oximetry, and plethymography would be considered part of EECP.

Indications for Catheter-based Intracoronary Brachytherapy:

- intracoronary vascular brachytherapy is indicated as an adjunct to PTCA, atherectomy, or stent implantation in patients with an in-stent restenosis of a native coronary artery; and
- other applications of intracoronary brachytherapy are considered INVESTIGATIONAL, including, but not limited to, the treatment of coronary stenoses unrelated to prior stent placement and the treatment of stenoses of non-native coronary vessels and, as such, are not covered under this policy.

Indications for ECP:

- members who have been diagnosed with disabling angina (Canadian Cardiovascular Society Class III or IV who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass because:
  - o their condition is inoperable, or they are at high risk of operative complications or post-operative failure;
  - o their coronary anatomy is not readily amenable to such procedures; or
  - o they have co-morbid states that create excessive risk.

Indications for TMLR:

- members who have been diagnosed with disabling intractable, (Canadian Cardiovascular Society Class III or IV) stable or unstable angina which has been found refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages in a hospital inpatient setting. In addition, the angina syndrome must be caused by areas of the heart not amenable to surgical therapies such as PTCA, stenting, coronary atherectomy, or coronary bypass; and
- coverage is further limited to those uses of the laser used in performing the procedure which have been approved by the FDA for the purpose for which they are being used.

  Members must meet additional selection guidelines:
  - ejection fraction ≥ 25%;
  - viable ischemic heart tissue as established by (unspecified) diagnostic study that cannot be revacularized by direct coronary vascularization; and
  - stable cardiovascular status with regard to severe ventricular arrhythmias, decompensated congestive heart failure or acute myocardial infarction.

Indications for Drug Eluting Stents:

- **Sirolimus-eluting stents are indicated to improve luminal diameter in vessels and lesions with the following characterics:**
  - native coronary arteries with reference diameter 2.5-3.5mm;
  - de novo vessel lesions lengths 8-33mm; and
  - antiplatelet therapy is required for a minimum of two months or up to six months following procedure.

- Paclitaxel-eluting stents are indicated to improve luminal diameter in vessels and lesions with the following characteristics:
  - native coronary arteries with reference diameter 2.5-3.75;
  - de novo vessel lesions less than 28mm in length; and
  - antiplatelet therapy is required for six months following procedure.

Exclusions/Limitations

Contraindications for Catheter-based Intracoronary Brachytherapy:

- recent evidence of a myocardial infarction within three (3) days prior to brachytherapy;
- history of prior radiotherapy to same arterial segment;
- evidence of severe peripheral vascular disease;
- child bearing potential;
- left main coronary artery disease;
- intraprocedural angiography shows evidence of thrombus, spasm or dissection;
- use of radioactive stent for prevention of restenosis and treatment of de novo lesions; and
- inability to maintain member on antiplatelet and/or anticoagulant therapy.

Contraindications for ECP: (Member is not a candidate for traditional CABG)

- left main coronary artery disease;
- cardiac catherization within one to two weeks;
- arrhythmia (e.g., atrial fibrillation, atrial flutter, ventricular tachycardia);
- congestive heart failure;
- aortic insufficiency;
  - evidence of an abdominal aortic aneurysm or severe ileofemoral occlusive disease;
- limiting peripheral vascular disease (PVD) and/or phlebitis;
- severe hypertension ≥ 180/110 mm Hg;
- bleeding diathesis or coumadin therapy with an INR ≥ 1.8;
- pregnancy or possible pregnancy; or
  - there is insufficient evidence that member will benefit from a second or subsequent ECP procedure, therefore, the benefit is restricted to a single course of treatment.

Limitations for Enhanced External Counterpulsation:

- there is insufficient evidence that there is benefit beyond a single course of therapy. Therefore, it would not be medically indicated for a member to receive more than one course of therapy;
- Canadian Cardiovascular Society Classification II angina;
- heart failure:
  - NYHA Class II/III stable heart failure symptoms with and ejection fraction of ≤ 35%;
  - NYHA Class II/III stable heart failure symptoms with and ejection fraction of ≤ 40%; or
  - NYHA Class IV;
- cardiogenic shock; and
- acute myocardial infarction.

Relative Contraindications for Transmyocardial Laser Revascularization (TMLR):

- unstable angina;
- recent myocardial infarct;
- depressed left ventricular ejection fraction (<25%); or
- pre-existing arrhythmias, CHF, Bleeding tendencies.

Limitations for Cypher™ Drug Eluting Stents Deployment:

- FDA has not approved use of drug eluting stents in vessels with a diameter < 2.5 or >3.5mm;
- safety and effectiveness has not been established in members with recent MI where there is evidence of thrombus or poor flow;
- safety and effectiveness has not been established in members with lesions located at the left main coronary artery, ostial lesions, lesions located at a bifurcation, diffuse disease, poor overflow distal to the identified lesions, or tortuous vessels in the region of the lesion;
- FDA has not approved drug eluting stents in lesions > 33mm or <8mm;

- member should be advised to avoid MRI imaging eight weeks or longer for adequate tissue coverage to occur over stent;
- drug eluting stents are contraindicated if member cannot take antiplatlet or anticoagulant therapy. If member has allergy to drug sirolimus (Rapamune®) or its derivatives polymers known as polymethacrylates or polyolefin;
- use of more than two Cypher™ stents has not been clinically evaluated and will result in member receiving larger amounts of drug and polymer; or
- the safety of and effectiveness of Cypher™ on a lesion previously targeted by brachytherapy has not been established. The safety and effectiveness of brachytherapy to treat Cypher™ in-stent restenosis have not been established. The synergy between two treatments has not been established. When more than one stent is required, resulting in stent to stent contact, the stent material should be similar.

Limitations for Express® drug eluting stent deployment:

- members in whom antiplatelet and/or anticoagulant therapy is contraindicated;
- members who have a lesion that prevents proper inflation of an angioplasty balloon or proper placement of the stent;
- use of more than one stent may result in member receiving larger amounts of drug and polymer than reflected in clinical trials. (In the instance of bailout stenting, another Express® can be used.);
- the safety of and effectiveness of Express® on a lesion previously targeted by brachytherapy has not been established. The safety and effectiveness of brachytherapy to treat Express® in-stent restenosis have not been established. The synergy between two treatments has not been established;
- safety and effectiveness has not been established in members with lesions located in the left main coronary artery, ostial lesions, lesions located at a bifurcation, diffuse disease, poor overflow distal to the identified lesions or tortuous vessels in the region of the lesion; or
- safety and effectiveness has not been established in members with recent MI where there is evidence of thrombus or poor flow.

Note: For Preferred Care authorization requirements refer to Appendix A and Appendix B in the Referral/Precertification/Prior Justification/Notification Administrative Policy. You may also refer to the "Prior Justification/Precertification of Certain Prescription Drugs" for information on drugs that require precertification and prior justification. Both policies are available on the easylink for Providers at www.preferredcare.org.

References

Literature (Search updated in 2006)

Centers for Medicare & Medicaid Services (CMS) 2006. Decision Memo for External Counterpulsation (ECP) Therapy (CAG-00002R2) Available on-line: http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=162.

Lemos, P., Saia, F., Hofman, SH, etal., Short- and Long-Term Clinical Benefits of Sirolimus-Eluting Stents Compared to Conventional Bare Metal For Patients

With Acute Myocardial Infarction, Journal of The American College of Cardiology. March 2004, Available: www.medscape.com.

ECRI, (March 2004). Drug-eluting coronary stents for treatment of coronary artery stenosis. Target database Technology assessment guide for emerging technologies. Available: www.target.ecri.org (membership required).

Boston Scientific, Directions for use, TAXUS Express2™, Paclitaxel-Eluting Coronary Stent System, Monorail® and Over the wire Coronary Stent Delivery System.

Cordis, A patient information guide for the Cypher ™ Sirolimus-eluting coronary stent.

Upstate Medicare Division, External Counterpulsation, Policy-CV005E00 [Online], 2003. Available: www.umd.nypic.com.

ECRI, (February 2003). FDA Advisory Committee Recommends Approving First Drug-Eluting Coronary Stent. HTA-news.

ECRI, (August 2002). Coated coronary stents may provide breakthrough for addressing restenosis. Technology Trends.

ECRI, (June 2002). Drug-eluting stents for the treatment of de novo coronary artery stenosis. Target Fact Sheet, No. 664.

Empire Medical Review Policy Issue, (February, 2002). Intravascular brachytherapy. The Medicare News Brief, MNB-Policy-2002-02, 18-21.

ECRI, (November 2000). Minimally invasive direct coronary artery bypass grafting (MIDCABG) on the beating heart for coronary artery disease. Windows on Medical Technology™, No. 41. [On-Line], 2002. Available: www.ecri.org.

ECRI, (November 2000). Catheter-based intravascular brachytherapy for prevention of coronary artery and in-stent restenosis. Target Fact Sheet, No. 796. [On-Line], 2001. Available: www.ecri.org.

ECRI, (April, 2001). Surgical transmyocardial laser revascularization for the palliation of intractable angina. Windows on Medical Technology™, No. 47.

Centers for Medicare & Medicaid Services (CMS) [formerly HCFA]. (April, 2001). Medical policies: External counterpulsation (ESP). Medicare B, 14-17.

ACC/AHA Task Force Report, (1991). Guidelines and indications for coronary artery bypass graft surgery, Journal of the American College of Cardiology, 17(3), 534-589.

Blue Cross/Blue Shield of Massachusetts, (1997). Coronary Heart Disease Advisory Group.

Centers for Medicare & Medicaid Services (CMS) [formerly HCFA]. (1999). Transmyocardial revascularization for severe angina-medicare coverage issues manual, [On-Line], 2000. Available: www.hcfa.gov.

ECRI, (1999). Transmyocardial revascularization (TMR) for intractable ishemic heart disease, [On-line], 2000. Available: www.healthcare.ecri.org.

AHA Medical/Scientific Statement Special Report, (1994). Optimal risk factor management in the patient after coronary revascularization, Circulation, 90, (6), 3125-3133.

A Consensus Development Conference Report to The National Advisory Committee on Core Health and Disability Support Services. (1993). Coronary artery bypass grafting and angioplasty, 1-27.

International Journal of Technology Assessment in Health Care, (1993). The appropriateness of the use of cardiovascular procedures: British versus U.S. perspectives, 9(1), 3-10.

Comparison of the appropriateness of coronary angiography and coronary artery bypass graft surgery between Canada and New York state, Journal of the American Medical Association, (1994). 272(12), 934-940.

The appropriateness of coronary artery bypass graft surgery in academic medical centers, (1996). Annals of Internal Medicine, 125(1), 8-18.

ACC/AHA Task Force Report, (1993). Guidelines for percutaneous transluminal coronary artery angioplasty, Journal of the American College of Cardiology, 22(7), 2033-54.

Health Technology Assessment Information Service, (1998). Transmyocardial laser revascularization for intractable ischemic heart disease (8).

Fishman, R., Harvey, S., Zellner, J., Pinosky, M., & Handy, J. (1998). Reducing cardiac surgical trauma: The minimally invasive direct coronary artery bypass. The Journal of the American College of Cardiology, 31, 1234-1239.

Wait, M.A. (1998). Direct coronary artery bypass (midcabg). What is the role of minimally invasive surgery in revascularization of patients? Journal of the Southern Medical Association.

ACC Educational Highlights/Fall 1998. Changing the business of heart surgery: The economics and future of minimally invasive cardiac surgery.

Vassilios, G., Knaut, M., Wagner, M., & Schuler, S. (1998). Minimally invasive surgical technique for the treatment on multi-vessel coronary artery disease, Cardiology Management.

ECRI, (1999). External counterpulsation for relief of angina. On-line], 2000. Available: www.healthcare.ecri.org.

Centers for Medicare & Medicaid Services (CMS) [formerly HCFA]. (1999). Enhanced counterpulsation for severe angina, [On-Line], 2000. Available: www.hcfa.gov.

University of California at San Franciso, Division of Cardiology (1998). ECP – external counterpulsation, [On-Line], 2000 Available: www.ucsf.edu/cardiology.

Approvals & Review/Revisions

Medical

Reviewed:
Medical Advisory Team: 5/23/06
Approved:
Clinical Quality Team: 7/17/06
Prior Approval Date: 9/12/05
Last Revision Date: 6/06
Origination Date: 6/96
Effective Date: 9/1/06