



INTRAVASCULAR BRACHYTHERAPY

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Status: Current

I. DESCRIPTION

Intravascular brachytherapy (IVBT) is the process of delivering a controlled dose of radiation to the target arterial lesion with the goal of reducing the incidence of restenosis following an interventional procedure. Radiation, either gamma (γ) or beta (β) is delivered to the affected vessel via a catheter-based system or radioactive stent. This is the primary treatment for coronary in-stent restenosis. IVBT has been shown to suppress neointimal growth, thus preventing restenosis after balloon angioplasty and stenting. Recent reports have suggested that IVBT may inhibit negative vessel remodeling after balloon angioplasty.

Intracoronary brachytherapy includes several techniques to deliver radiation locally to coronary blood vessels by means of catheters or stents. It is used to reduce the rate of restenosis following revascularization of obstructed vessels by percutaneous coronary intervention (PCI), formerly called percutaneous transluminal coronary angioplasty (PTCA).

Interventional cardiologists now place metal stents after dilating an obstructed artery in 85–90% of cases, because doing so has substantially reduced the previously reported rate of restenosis (35–45%) to a level of 15–25%. It has been determined in a 12 month follow up that the incidence of target lesion repeat stenosis was significantly lower at 12 months follow-up among patients implanted with a slow-release paclitaxel-eluting coronary stent (PES), compared with those allocated the bare-metal stent. Paclitaxel is a chemotherapy drug.

The slow-release paclitaxel eluting coronary stent is only for use in patients with symptomatic coronary artery disease (CAD) associated with stable or unstable angina pectoris or silent ischemia caused by a single, de novo stenosis of a native coronary artery that is 2.5 mm to 3.75 mm in diameter and 10 to 28 mm in length, and is coverable with one to two stents.

Elastic recoil, excessive neointimal proliferation, and late contraction, or remodeling, have been suggested as the primary mechanisms of restenosis. Neointimal hyperplasia is a proliferative response to overstretch balloon injury, which mimics the scar tissue formation seen in other tissues during the healing process. Local ionizing radiation has significantly reduced neointimal

proliferation in animal models. Presumably, the theoretical benefit of radiation resides in its killing effect of rapidly dividing smooth muscle cells and the inhibition of the recruitment and proliferation of adventitial myofibroblasts.

The objective of intracoronary brachytherapy is to prevent or further reduce the rate of coronary restenosis and thus improve overall health outcomes.

II. POLICY/CRITERIA

- A. Intracoronary brachytherapy with gamma or beta radioactive ribbons for the management of in-stent restenosis of native coronary vessels following successful PTCA is a covered benefit.
- B. Intracoronary brachytherapy for non-stented lesions, or for any type of lesion utilizing any other source (e.g., with radioactive stents) is not a covered benefit.

NOTE: Currently, the Cordis Checkmate System, the NOVOSTE Beta-Cath System, and the Galileo Intravascular Radiotherapy System (Guidant Corp.) are FDA approved for brachytherapy.

- C. Clear patient selection criteria have not been fully established at this time. Catheter-based brachytherapy is indicated for the treatment of ischemic patients with restenotic in-stent lesions of a major native coronary artery.
- D. Contraindications for intracoronary brachytherapy are as follows:
 - Evidence of myocardial infarction within 3 days prior to brachytherapy
 - Contraindication to aspirin, ticlopidine, or stainless steel
 - Prior chest radiotherapy
 - Life-threatening coexisting condition
 - Severe peripheral vascular disease
 - Child-bearing potential
 - Anticipated difficulty with follow-up
 - Serum creatinine > 2.0 mg/dL
 - Left ventricular ejection fraction < 40%
 - Unprotected left main coronary artery disease
 - Lesion angulation > 45
 - Intraprocedural angiographic evidence of thrombus, spasm, or dissection
 - Multiple lesions in the same vessel
 - Bifurcation or aorto-ostial lesions
 - Non-FDA approved radiation delivery devices
 - Non-FDA approved uses (i.e. target lesions) of radiation delivery devices

Rationale

Intravascular brachytherapy (IVBT) is the primary treatment for coronary in-stent restenosis. Interventional cardiologists now place metal stents after dilating an obstructed artery in 85–90% of cases, because doing so has substantially reduced the previously reported rate of restenosis (35–45%) to a level of 15–25%. The objective of intracoronary brachytherapy for in-stent restenosis following

successful PTCA is to prevent or further reduce the rate of restenosis of the targeted arterial lesion.

III. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

IV. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS).*
- ❖ **MEDICAID:** *If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule, the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--00.html will govern.*
- ❖ **MICHILD:** *For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.*

V. CODING INFORMATION

ICD-9 Codes that may support medical necessity

410.00-410.92 Acute myocardial infarction
411.0-411.89 Other acute and subacute forms of ischemic heart disease
412 Old myocardial infarction
413.0-413.9 Angina pectoris
414.00-414.9 Coronary atherosclerosis
996.00 Mechanical complication of unspecified cardiac device, implant, and graft
996.72 Other complications due to other Cardiac device, implant and graft
V45.82 Percutaneous transluminal coronary angioplasty status

CPT/HCPCS Codes

92974 Transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy (List separately in addition to code for primary procedure – one of the following codes)

- 92980 Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel
- 92981 Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel (List separately in addition to code for primary procedure)
- 92982 Percutaneous transluminal coronary balloon angioplasty; single vessel
- 92984 Percutaneous transluminal coronary balloon angioplasty; each additional vessel (List separately in addition to code for primary procedure)
- 92995 Percutaneous transluminal coronary atherectomy, by mechanical or other method, with or without balloon angioplasty; single vessel
- 92996 Percutaneous transluminal coronary atherectomy, by mechanical or other method, with or without balloon angioplasty; each additional vessel (List separately in addition to code for primary procedure)
- 93508 Catheter placement in coronary artery(s), arterial coronary conduit(s), and/or venous coronary bypass graft(s) for coronary angiography without concomitant left heart catheterization
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- 77785 Remote afterloading high dose rate radionuclide brachytherapy; 1 channel
- 77786 Remote afterloading high dose rate radionuclide brachytherapy; 2-12 channels
- 77787 Remote afterloading high dose rate radionuclide brachytherapy; over 12 channels

VI. REFERENCES:

1. Blue Cross Blue Shield. (2002). Intracoronary brachytherapy as an adjunct to percutaneous revascularization to prevent and manage restenosis. TEC Assessment Program 17 (9).
2. HAYES Alert. Intracoronary beta radiation for in-stent restenosis (VIII:7). Lansdale, PA: HAYES, Inc.; March 2002.
3. HAYES Alert. Long-term results of intracoronary radiation therapy (VII:2). Lansdale, PA: HAYES, Inc.; February 2004.
4. HAYES Medical Technology Directory. Drug-eluting stents for treatment of coronary artery disease (DRUG102.04). Lansdale, PA; HAYES, Inc.; August 2003.
5. HAYES Medical Technology Directory. Intracoronary Radiation Therapy (INTRO301.33). Lansdale, PA: HAYES, Inc.; November 2000.
6. Singh, H, MS, Yue, N, PhD, Azimi, A, MD, et al, "Relation of clinical success in coronary brachytherapy to dose." American Journal of Cardiology, Volume 94, Number 7, October 1 2004.

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