

Evidence Based Guideline

Brachytherapy, Intracoronary

File Name: brachytherapy_intracoronary
Guideline Number: EBG.RAD5074
Origination: 10/2000
Last Review: 6/2009

Active guideline, no longer scheduled for routine literature review.

Description of Procedure or Service

Intravascular brachytherapy in conjunction with percutaneous transluminal angioplasty (PTA) has been investigated primarily in the coronary arteries but also in the femoropopliteal system. In the coronary arteries, two clinical applications of intravascular brachytherapy have been investigated:

1. As a technique to reduce the risk of de novo restenosis after intracoronary stent placement (i.e., in-stent restenosis)

The risk of restenosis in patients who undergo percutaneous transluminal coronary angioplasty (PTCA) for coronary artery disease is estimated at 30%–50%, based on angiographic studies. Placement of stents as an adjunct to PTCA is one strategy to reduce restenosis; it is estimated that approximately 75% of PTCAs performed in the United States includes stent placement. However, even with stent placement, the restenosis rate (i.e., in-stent restenosis) is estimated at 20%. Intracoronary radiation has been investigated both as an alternative to stent placement to reduce the risk of restenosis and as an adjunctive technique at the time of stent placement to reduce the risk of in-stent restenosis. These applications of intracoronary brachytherapy are off-label indications.

2. As a treatment of restenosis at the site of a prior intracoronary stent

As noted here, there is about a 20% risk of in-stent restenosis. Management of in-stent restenosis is notoriously ineffective, with recurrence rates of 30%–70%. Management has included PTCA alone, restenting, laser angioplasty, and rotational atherectomy. These therapies, however, are often ineffective, requiring medical management or surgical revascularization. Intracoronary brachytherapy is an alternative to these therapies for managing in-stent restenosis.

Intravascular brachytherapy has also been investigated as an adjunct to percutaneous transluminal angioplasty of the femoropopliteal systems, as a technique to reduce the risk of a de novo restenosis, either in native or grafted vessels, and with or without stent placement. The greatest amount of clinical experience with intravascular brachytherapy is in the coronary artery system. However important differences preclude extrapolating results from coronary to peripheral arteries. There is greater anatomic variability in peripheral arteries than in coronary arteries in factors such as length, diameter, thickness, curvature, and orientation. The larger size of peripheral arteries necessitates treatment with a high-energy gamma radiation source rather than beta radiation, which is more commonly used for the coronary arteries. High-energy radiation sources cannot be administered in most catheterization laboratories or radiology suites, necessitating treatment in the radiation oncology department, which increases logistical complexity for treating peripheral vessels. The use of adjunctive agents, such as stenting and antiplatelet drugs, while extremely common in the coronary arteries, is not as well established for peripheral angioplasty. Stenting has not been definitively shown to be superior to angioplasty alone, although it is used by many experts for certain types of lesions such as longer segments of the iliac artery or ostial lesions of the aortic branch vessels.

Policy: Brachytherapy, Intracoronary

The U.S. Food and Drug Administration (FDA) has approved devices intended for use in intracoronary brachytherapy, the Beta-Cath system (Novoste Corp), which delivers beta radiation, and the CheckMate system (Cordis), which delivers gamma radiation. In 2001, a second beta radiation device, the Galileo Intravascular Radiotherapy System (Guidant), was approved. Both of the beta devices have similar labeling approved by the FDA that limits the approved use of the devices to delivery radiation to “the site of successful percutaneous coronary intervention” for the treatment of in-stent restenosis in native coronary arteries with discrete lesions. The wording of the gamma device’s approval is slightly different, saying it is “for use in the treatment of native coronary arteries with in-stent restenosis following percutaneous revascularization using current interventional techniques.” There are currently no brachytherapy devices approved specifically for use in the peripheral arterial system. As of May 2007, the CheckMate and Galileo systems and devices for intravascular brachytherapy are no longer available, having been discontinued by their respective manufacturers. The Beta-Cath system is now manufactured and distributed by Best Vascular Inc.

Evidence Based Guideline for Intracoronary Brachytherapy

Intravascular coronary brachytherapy using gamma or beta-emitting radiation may be appropriate to treat restenosis of a previously-placed bare-metal stent in a native coronary artery.

Intravascular coronary brachytherapy using only gamma radiation may be appropriate to treat in-stent restenosis of a non-native coronary artery (i.e., saphenous vein graft).

Medical Evidence regarding Intracoronary Brachytherapy indicates it is not recommended in the following situations:

Intravascular coronary brachytherapy using gamma or beta-emitting radiation is not recommended to treat or prevent restenosis of drug-eluting stents.

Intravascular coronary brachytherapy to reduce the risk of de novo restenosis, in conjunction with PTA with or without stent placement, is not recommended

Intravascular brachytherapy of the femoropopliteal system is not recommended.

Benefits Application

Please refer to certificate for availability of benefit. This guideline relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 77799, 92974

Scientific Background and Reference Sources

TEC Assessment, Volume 14, No. 2, 5/99
BCBSNA Medical Policy Reference Manual, 2.02.11, 7/16/99
Specialty Matched Consultant Advisory Group - 9/00
Medical Policy Advisory Group - 10/00
BCBSA Medical Policy Reference Manual, 2.02.11, 5/31/01
Specialty Matched Consultant Advisory Group - 12/2001
BCBSA Medical Policy Reference Manual, 2.02.11, 7/12/02
BCBSA Medical Policy Reference Manual, 2.02.11, 12/18/02
Specialty Matched Consultant Advisory Group - 11/2003
Specialty Matched Consultant Advisory Panel - 11/2005
BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.11, 7/10/08

Policy Implementation/Update Information

9/00 Specialty Matched Consultant Advisory Group
10/00 Original policy issued. Medical Policy Advisory Group - Approved.
5/01 Changes in formatting.
12/01 Specialty Matched Consultant Advisory Group review. Policy clarified. Revised to include eligible indication. Policy name changed from Intracoronary Radiation after PTCA.
9/02 Clarified Description, When it is Covered and When it is Not Covered sections of the policy. Added code 92974 to policy. Policy name changed from Brachytherapy, Intracoronary after PTCA to Brachytherapy, Intracoronary. Added saphenous vein graft as a covered indication with selection criteria.
1/03 Statement added to Billing/Coding Section indicating that Medical Records may be ordered.
11/03 Biannual policy review. Specialty Matched Consultant Advisory Panel review. No change to policy. Reformatted for consistency.
11/17/05 Biennial policy review. Specialty Matched Consultant Advisory Panel review 11/7/05. No change to policy. Policy reflects current standard of care. Policy status changed to "Active policy, no longer scheduled for routine literature review."
5/11/09 CPT Code 77781 deleted. (adn)
7/20/09 Description section extensively revised. The When Covered section was revised to read: Intravascular coronary brachytherapy using gamma or beta-emitting radiation may be considered medically necessary to treat restenosis of a previously-placed bare-metal stent in a native coronary artery. Intravascular coronary brachytherapy using only gamma radiation may be considered medically necessary to treat in-stent restenosis of a non-native coronary artery (i.e., saphenous vein graft). The When Not Covered section was revised to read: Intravascular coronary brachytherapy using gamma or beta-emitting radiation is considered investigational to treat or prevent restenosis of drug-eluting stents. Intravascular coronary brachytherapy to reduce the risk of de novo restenosis, in conjunction with PTA with or without stent placement, is considered investigational. Intravascular brachytherapy of the femoropopliteal system is considered investigational. (adn)

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7/20/09 Medical Policy changed to Evidence Based Guideline.

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.