Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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Category: Medicine
***Current Policy Effective Date: 9/1/09**

Title: Brachytherapy of the Femoropopliteal Arterial System after Percutaneous Transluminal Angioplasty (PTA)

Procedure Code(s): 37799

Description / Background

Peripheral arterial disease (PAD) of the femoropopliteal system is a major cause of morbidity and limb loss. Medical therapy is often ineffective in controlling symptoms and preventing disease progression. Surgical bypass may be effective treatment for patients who fail medical therapy or who have limb-threatening ischemia. Percutaneous transluminal angioplasty (PTA) is a less-invasive alternative to open surgery and has been utilized for several decades in the femoropopliteal system. The main limitation of femoropopliteal PTA is "late" restenosis (within 6 months of the procedure) which occurs at rates even higher than with coronary PTA or with PTA of other peripheral vascular systems such as the aortoiliac system. In addition, the high restenosis rate has not been reduced by the use of adjunctive agents such as stents.

Peripheral artery brachytherapy involves the delivery of radiation to peripheral arteries through local catheters, and is intended to reduce restenosis following PTA. Brachytherapy *may* reduce the rate of late restenosis following PTA and therefore reduce the need for further revascularization procedures, especially open surgery. It may also improve outcomes of PAD such as symptoms, exercise tolerance and reduce the need for amputation. However, there is no conclusive evidence to determine whether peripheral artery brachytherapy improves outcomes when used as an adjunct to PTA in the femoropopliteal system.

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

*See current effective policy date, if applicable
**See section "CPT/HCPCS Level II Codes and Description" for code nomenclature and for additional code(s) if applicable.

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de novo restenosis, either in native or grafted vessels, either with or without stent placement. The greatest amount of clinical experience with intravascular brachytherapy is in the coronary artery system. However, many differences between the coronary and peripheral arterial systems would preclude extrapolation of results from one system to another. There is greater anatomic variability in peripheral arteries than 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 the 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. This makes the logistics of treatment of the peripheral arteries more complex compared to the coronary arteries. 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 for certain types of lesions such as longer segments of the iliac artery or ostial lesions of the aortic branch vessels.

There are no brachytherapy devices approved for use in the peripheral arterial system.

CPT / HCPCS Level II Codes and Description *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

37799 Unlisted procedure, vascular surgery
There is no established code for this service.

Diagnoses / Medical Conditions

Peripheral vascular disease

Medical Policy Statement

Intravascular brachytherapy of the femoropopliteal system is experimental/investigational. It has not been demonstrated to be as safe and effective as conventional treatment.

Rationale

The evidence in the medical literature does not permit conclusions as to whether peripheral artery brachytherapy, as an adjunct to PTA for the prevention of restenosis in the

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femoropopliteal system, improves health outcomes or is as beneficial as any established alternatives. In addition, there are currently no brachytherapy devices approved for use in the peripheral arterial system.

The policy regarding intravascular femoropopliteal radiation therapy is based on a 2002 BCBS Association TEC Assessment that offered the following observations and conclusions:

1. The scientific evidence consisted of two randomized trials comparing PTA plus brachytherapy with angioplasty alone. Both trials had limitations that precluded conclusions on whether brachytherapy is efficacious for the population under consideration. The Vienna-2 trial was unblinded and had no placebo control. It also enrolled heterogeneous subgroups of patients. The second trial was single blinded with a sham brachytherapy placebo control. However, this trial only reported on 22 patients and used an unusual outcome measure as primary outcome.
2. The TEC Assessment concluded that the evidence was insufficient to permit scientific conclusions regarding brachytherapy as an adjunct to peripheral artery angioplasty.

Two studies reported long-term follow-up after endovascular brachytherapy to prevent restenosis in femoropopliteal arteries treated with balloon angioplasty (Wolfram, et al. and Diehm, et al). Both reported that brachytherapy delayed restenosis when measured after short-term follow-up, but these benefits were not sustained and the rates of restenosis were similar in treated and control groups with longer follow-up.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

The majority of peripheral arterial disease (PAD) in the lower extremities is due to blockages in the blood vessels from the upper thigh to past the knee. Current therapy for symptomatic PAD include exercise and smoking cessation, low-dose aspirin, lowering cholesterol levels, percutaneous transluminal angioplasty (PTA) and surgery to bypass the blockage. When PTA is done, the chance of repeat restenosis or blockage is 40%. Studies have been done to see if radiation treatment (brachytherapy) after PTA can reduce the rate of repeat stenosis or blockage. These studies have been unable to determine what the long-term effects of brachytherapy are following PTA and if they improve outcomes when used in addition to PTA.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

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Related Policies

Brachytherapy of the Breast

Medicare Information

Local Michigan Medicare contractor's determination number CV-035, "Intravascular Brachytherapy (IVBT)" states "intravascular brachytherapy is only covered for native coronary in-stent restenosis," revision effective date 12/01/2002.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

References

- Blue Cross Blue Shield Association "Brachytherapy for the Prevention of Restenosis in Peripheral Arteries Following PTA of the Femoropopliteal System," *Technology Evaluation Center (TEC) Assessment Program,* Volume 17, Number 22, February 2003.
- Blue Cross Blue Shield Association, "Intra-arterial Brachytherapy for Prevention and Management of Restenosis after Percutaneous Transluminal Angioplasty (PTA)," *Medical Policy Reference Manual*, Policy #2.02.11, original policy date 7/16/99, last review date 7/1/08.
- Davies, Mark G., MD, David L. Waldman, MD and Thomas A. Pearson, MD, "Comprehensive Endovascular Therapy for Femoropopliteal Arterial Atherosclerotic Occlusive Disease," *J Am Coll Surg,* Volume 201, Number 2, August 2005, pp. 275-297.
- Krueger, K., et al., "De novo femoropopliteal stenoses: endovascular gamma irradiation following angioplasty-angiographic and clinical follow-up in a prospective randomized controlled trial," Radiology, Volume 231, Number 2, May 2004, pp. 546-554.
- Diehm, Nicolas A., MD, et al., "Endovascular Brachytherapy after Femoropopliteal Balloon Angioplasty Fails to Show Robust Clinical Benefit Over Time," *J Endovasc Ther*, Volume 12, Number 2005, pp.723–730.
- Wolfram, Roswitha M., MD, et al., "Endovascular Brachytherapy for Prophylaxis of Restenosis after Femoropopliteal Angioplasty: Five-year Follow-up-Prospective Randomized Study," *Radiology*, Volume 240, 2006, pp. 878-884.
- Wolfram, Roswitha M., MD, et al., "Endovascular Brachytherapy for Prophylaxis against Restenosis after Long-Segment Femoropopliteal Placement of Stents: Initial Results," *Radiology,"* Volume 220, Number 3, September 2001, pp. 724-729.

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- Wyttenbach, R., et al., "Effects of percutaneous transluminal angioplasty and endovascular brachytherapy on vascular remodeling of human femoropopliteal artery: 2 years follow-up by noninvasive magnetic resonance imaging," *Eur J Vasc Endovasc Surg*, Volume 34, Number 4, October 2007, pp. 416-423.
- Wisconsin Physicians Service (WPS), "Intravascular Brachytherapy (IVBT)," *WPS Local Medical Review Policy*, CCV-035, original Michigan effective date 11/5/01, most recent Michigan revision date 1/1/08, < http://www.wpsmedicare.com/part_b/policy/cv035.pdf > (May 8, 2009).

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through May 7, 2009, the date the research was completed.

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Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/21/03	7/21/03	7/21/03	Joint medical policy established.
4/5/05	4/5/05	4/5/03	Scheduled review for investigational policy.
5/1/07	3/1/07	3/4/07	Routine maintenance.
9/1/09	6/16/09	6/16/09	Routine maintenance; policy retired.

Next Review: This treatment/procedure has been determined to be obsolete and is no longer subject to routine review.

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: N/A	Revised: N/A

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BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BRACHYTHERAPY OF THE FEMOROPOPLITEAL ARTERIAL SYSTEM AFTER PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA)

I. Short Description

Intravascular brachytherapy has been investigated as an adjunct to percutaneous transluminal angioplasty of the femoropopliteal systems, as a technique to reduce the risk of restenosis, either in native or grafted vessels, either with or without stent placement. The greatest amount of clinical experience with intravascular brachytherapy is in the coronary artery system. However, there is greater anatomic variability in peripheral arteries than 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 the beta radiation, which is more commonly used for the coronary arteries.

The evidence in the medical literature does not permit conclusions as to whether peripheral artery brachytherapy, as an adjunct to PTA for the prevention of restenosis in the femoropopliteal system, improves health outcomes or is as beneficial as any established alternatives. In addition, there are currently no brachytherapy devices approved for use in the peripheral arterial system. Therefore, intravascular brachytherapy of femoropopliteal arteries is considered experimental/investigational.

II. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	Not covered.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
BlueCaid	Not covered.

III. Administrative Guidelines:

N/A

IV. Effective Dates:

Policy updated: 4/05/05, 5/1/07, 9/1/09
Joint policy effective date: 7/21/03

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