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1.0 Description of the Procedure, Product, 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:

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

The risk of re-stenosis in recipients 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 re-stenosis; it is estimated that approximately 75% of PTCAs performed in the United States includes stent placement. However, even with stent placement, the re-stenosis rate (i.e., in-stent re-stenosis) is estimated at 20%. Intracoronary radiation has been investigated both as an alternative to stent placement to reduce the risk of re-stenosis and as an adjunctive technique at the time of stent placement to reduce the risk of in-stent re-stenosis. These applications of intracoronary brachytherapy are off-label indications.

- b. As a treatment of re-stenosis at the site of a prior intracoronary stent.

As noted here, there is about a 20% risk of in-stent re-stenosis. Management of in-stent re-stenosis is notoriously ineffective, with recurrence rates of 30%–70%. Management has included PTCA alone, re-stenting, 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 re-stenosis.

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 re-stenosis, 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.

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 re-stenosis 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 re-stenosis 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.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient’s needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient’s caretaker, or the provider.

3.2 Specific Criteria

There are no criteria for coverage of intracoronary brachytherapy. Claims for this service are processed without review of criteria.

3.3 Other Medical Policy Guidelines

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

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

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

There are no specific criteria for not covering intracoronary brachytherapy. Refer to **Subsection 4.3**.

4.3 Policy Guidelines

Medical evidence regarding intracoronary brachytherapy indicates it is not recommended in the following situations:

- a. Intravascular coronary brachytherapy using gamma or beta-emitting radiation is not recommended to treat or prevent re-stenosis of drug-eluting stents.
- b. Intravascular coronary brachytherapy to reduce the risk of de novo re-stenosis, in conjunction with PTA with or without stent placement, is not recommended.
- c. Intravascular brachytherapy of the femoropopliteal system is not recommended.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for intracoronary brachytherapy.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
September 30, 2011	Throughout	Policy Date of Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Code(s)
77799
92974

Note: 77799 may suspend for medical review.

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital and Outpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.