INTRAVASCULAR BRACHYTHERAPY FOR PREVENTING AND MANAGING RESTENOSIS AFTER PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Brachytherapy describes the delivery of radiation therapy via radioactive ribbons or seeds, radioactive stents, or radioactive filled catheter balloons. The radioactive source (gamma, beta or alpha radioisotopes) is implanted within, or close to, the targeted site, allowing a high dose of radiation with less exposure to normal cells. Implants may be intracavity, interstitial or intraluminal and permanent or temporary.

Intravascular brachytherapy in conjunction with percutaneous transluminal angioplasty (PTA) has been investigated primarily in the coronary arteries but also in the femoropopliteal system.
INTRAVASCULAR BRACHYTHERAPY FOR PREVENTING AND MANAGING
RESTENOSIS AFTER PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA)
(cont.)

Criteria:

- Brachytherapy for restenosis of a previously placed bare metal stent is considered medically necessary with documentation of ALL of the following:
  1. Site of restenosis:
     - Native coronary artery (at a prior PTCA and/or stent site) or
     - Non-native coronary artery (e.g., saphenous vein graft, inframammary vein graft)
  2. Delivery route via gamma or beta radioactive ribbons or seeds
  3. Treatment occurs after percutaneous transluminal coronary angioplasty (PTCA)

- Brachytherapy for the following indications is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational settings.

These indications include, but are not limited to:

- As an adjunct to PTCA to prevent restenosis of an initial lesion (de novo) in the coronary artery
- Prevention of restenosis of drug-eluting stents
- Treatment of restenosis of drug-eluting stents
- Utilizing a radioactive source other than gamma or beta (e.g., alpha)
INTRAVASCULAR BRACHYTHERAPY FOR PREVENTING AND MANAGING RESTENOSIS AFTER PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) (cont.)

Criteria: (cont.)

- Intravascular brachytherapy delivered by any other method other than ribbons or seeds (e.g., radioactive stents, catheter balloons) is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  3. Insufficient evidence to support improvement outside the investigational setting.

- Brachytherapy to prevent restenosis of the femoropopliteal system as an adjunct to percutaneous transluminal angioplasty (PTA) is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational settings.

Resources:

Resources prior to 10/29/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


3. InterQual® Care Planning, Procedures. Percutaneous Coronary Interventions (PCI).
