Intra-arterial Brachytherapy for the Management and Treatment of Restenosis after Percutaneous Transluminal Angioplasty (PTA)

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Policy # 00076
Original Effective Date: 01/27/2003
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider the use of intravascular coronary brachytherapy using gamma radiation or beta–emitting radiation as a treatment of in-stent restenosis of a native coronary artery to be eligible for coverage.

Based on review of available data, the Company may consider the use of intravascular coronary brachytherapy using gamma radiation only as a treatment of in-stent restenosis of a non-native coronary artery i.e., saphenous vein graft to be eligible for coverage.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of intracoronary brachytherapy as a treatment to reduce the risk of a de novo restenosis in conjunction with percutaneous transluminal angioplasty with or without stent placement to be investigational.*

Based on review of available data, the Company considers the use of intravascular brachytherapy of the femoropopliteal system to be investigational.*

Background/Overview
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:

*Please note that this section is marked as investigational, indicating that further research is required before it can be considered for routine use.

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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 PTA of the femoropopliteal systems, as a technique to reduce the risk of 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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
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The 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 of 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.

Rationale/Source
This policy regarding intravascular coronary radiation therapy is based on a 2000 TEC Assessment that offered the following observations and conclusions:

- There are four well-designed randomized clinical trials evaluating the effectiveness of brachytherapy for managing in-stent restenosis in native coronary vessels. The outcomes of these trials indicate that patients with in-stent restenosis treated with brachytherapy do better than patients treated with PTCA alone or with PTCA and stenting. Angiographic data at 6 to 9 months show significant reduction in the restenosis rate in brachytherapy patients. More importantly, patients receiving brachytherapy have statistically significant reduction in target lesion revascularization rates.
- There are no randomized controlled trials supporting the use of intracoronary brachytherapy for the prevention of restenosis.

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

- 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.
- The TEC Assessment concluded that the evidence was insufficient to permit scientific conclusions regarding brachytherapy as an adjunct to peripheral artery angioplasty.
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Waksman and colleagues reported on the results of a trial that randomized 120 patients with in-stent restenosis in saphenous vein grafts (SVG) to receive standard angioplasty and stenting or standard treatment plus intravascular gamma irradiation. At six months, the restenosis rate was lower in those receiving intracoronary irradiation. As noted here, the FDA labeling for intracoronary brachytherapy is limited to its use as a treatment of in-stent restenosis, and its use for primary prevention of in-stent restenosis remains investigational. Serruys and colleagues reported on the results of a randomized trial of intracoronary brachytherapy as primary prevention in 112 patients. The authors reported that the clinical outcomes of the irradiated group were inferior to those of the non-irradiated control group.

Studies are emerging that focus on the long-term outcomes of intracoronary brachytherapy. Of particular concern is the incidence of late stent restenosis. While conventional treatment of in-stent restenosis is associated with early thrombosis, late stent restenosis is uncommon. Grise and colleagues reported a 5-year follow-up of 55 patients enrolled in a clinical trial of gamma irradiation as a treatment of in-stent restenosis. Target lesion revascularization was required in 23.1% of the treatment group compared to 48.3% in the control group. There were two late revascularizations between 3 and 5 years in the treatment group, compared to none in the control group. Long-term anticoagulation therapy has been proposed as a strategy to reduce the incidence of late thrombosis. Meerkin and colleagues focused on the 2-year follow-up of 30 patients treated with intracoronary beta irradiation. Late failures occurred in 7 of the 30 patients. Studies have also been reported on intracoronary beta irradiation with a novel liquid rhenium-188-filled balloon catheter with favorable outcomes.

With the success of rapidly evolving drug-eluting stents (DES), trials comparing brachytherapy to DES are needed to determine the appropriate role of brachytherapy in the treatment and prevention of restenosis. For example, Pohl and colleagues compared outcomes of 28 patients treated with intracoronary brachytherapy for in-stent restenosis with 28 patients treated with the implantation of a sirolimus-eluting stent for in-stent restenosis during two time-frames. The authors found a lower incidence of recurrence of in-stent restenosis in patients treated with sirolimus-eluting stents. In addition, treatment with sirolimus-eluting stent implantation appeared to be safe and had a lower rate of late luminal loss than treatment with brachytherapy. The use of complex intravascular brachytherapy has been decreasing with the use of DES, and its future role in the treatment of in-stent restenosis is uncertain.

Regarding femoropopliteal irradiation as an adjunct to peripheral angioplasty and stenting, data continue to be inconclusive. Bonvini and colleagues reported on interim results of an ongoing randomized trial, focusing on thrombotic occlusion in those randomized to receive intravascular gamma irradiation. Late occlusion was reported in 27% of those in the irradiated group compared to none in the control group. In the Vienna-3 trial, Pokrajac and colleagues reported restenosis rates to be significantly lower at 12-month follow-up in 134 patients randomized after femoropopliteal angioplasty to brachytherapy (41.7%) versus sham irradiation (67.1%). However, the authors acknowledged some study limitations (small study size, high drop-out rate.
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and angiographic follow-up in only 81% of patients). The Vienna-5 trial randomized 88 patients to PTA and femoropopliteal stent implantation with either gamma brachytherapy or sham irradiation and found no difference in recurrence rates at the 6- and 12-month follow-up between the two groups (33% with brachytherapy vs. 35% without at six months; and 59% with brachytherapy vs. 43% without at 12 months).

Treating restenosis of bare-metal stents in native coronary arteries:
A recent meta-analysis pooled data from 11 separate randomized controlled trials (RCTs) comparing vascular brachytherapy versus PTA, with or without stent placement. In seven of these trials, all patients were treated for in-stent restenosis, while four trials enrolled mixed populations (i.e., some primary lesions). In the seven trials on pure in-stent restenosis, vascular brachytherapy significantly reduced the rate of major adverse cardiovascular events (MACE; RR=0.58; 95% CI: 0.50–0.67; p<0.001), restenosis (RR=0.55; 95% CI:0.48–0.64; p<0.001), and late lumen loss (standard mean difference = –0.69; 95% CI: –0.92, –0.46; p<0.001) at intermediate time points (defined as 6–24 months). Only five trials reported long-term outcomes (more than three years), of which, only three studied pure in-stent restenosis. Major adverse cardiovascular events were the only long-term outcome significantly reduced by vascular brachytherapy.

Three RCTs have directly compared vascular brachytherapy versus DES as treatments for in-stent restenosis. Two of these were large, multicenter trials that randomized nearly 400 patients each, while the third was a single-center trial that closed early (n=37) because the vascular brachytherapy devices were no longer available. In each of the two completed trials, DES significantly decreased the rate of target lesion revascularization and angiographic restenosis at 6 to 9 months by about half, when compared with vascular brachytherapy. However, longer-term follow-up data were not reported. Editorials published at the same time as these reports cited the marked decline in use of bare-metal stents for primary percutaneous interventions. The editorialists also had reservations about generalizing results from RCTs of vascular brachytherapy for restenosis in bare-metal stents to draw conclusions about effectiveness of vascular brachytherapy to treat restenosis in DES.

Treating restenosis in drug-eluting stents:
Two clinical series reported on use of vascular brachytherapy to treat restenosis in a DES. One series (n=61) compared outcomes with a prior consecutive series (n=50) treated with repeat DES. At eight months after treatment, rates of target lesion and target vessel revascularization were similar in the two series, although the MACE rate was smaller in the vascular brachytherapy group than in the repeat DES group (9.8% vs. 2.4%; p=0.044). The second series only included five patients, all with recurrent stenosis after sequential treatment with sirolimus- and paclitaxel-eluting stents. Further study is needed to determine if vascular brachytherapy is useful to treat restenosis in DES.
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In-stent restenosis in SVGs: The 2007 literature search did not identify any new studies that might alter the recommendation of this policy that vascular brachytherapy may be considered medically necessary to treat in-stent restenosis of SVGs.

Preventing restenosis after primary PTCA with or without stent placement:
Five studies reported on use of vascular brachytherapy to prevent restenosis after primary percutaneous interventions, including three with long-term (3.8-5 years) follow-up and two with intermediate-term (9-16 months) follow-up. The studies with long-term follow-up reported that early benefit from vascular brachytherapy was not sustained because of delayed and progressive restenosis and thrombotic complications. In one of the studies, the delayed restenosis and thrombosis occurred despite the use of combined antiplatelet therapy.

Treating or preventing restenosis after angioplasty in femoropopliteal arteries:
Two studies reported long-term follow-up after endovascular brachytherapy to prevent restenosis in femoropopliteal arteries treated with balloon angioplasty. 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.

The policy was updated with a MEDLINE search for the period May 2007 to June 2008. No studies were identified that would change the coverage statement. For the treatment of bare metal stent restenosis, the previous update states that long-term follow-up comparing DES to vascular brachytherapy is needed, given that the available studies were limited to nine months of follow-up. Three studies were identified that address this issue; two randomized controlled trials reporting one year (n=129) and two year (n=396) clinical outcomes and a retrospective cohort study with three year (n=360) outcomes. Most failure was symptom related in these studies as protocol angiography was limited to the initial 6 or 9 month follow-up. Park reported one year MACE rates of 7.7% vs. 18.8% (p=0.07) in a study of 129 patients from Asia in the DES (sirolimus) and vascular brachytherapy groups respectively. This was driven primarily by statistically improved target lesion revascularization rates of 4.6% versus 18.8% (p=0.01). Ellis et al reported two year target lesion revascularization rates of 10.1% and 21.6% (p=0.03, n=396) in the DES (pacltaxel) and brachytherapy groups, respectively. However, there were no significant differences between the two groups with regard to death, myocardial infarction (MI) or target vessel thrombosis at 24 months. A five year follow-up for this study is planned. Last, 3-year MACE-free survival was 92.5% in the DES (sirolimus) treated cohort and 82.4% (p=0.03) in the brachytherapy cohort in a retrospective registry review of 360 patients from Asia reported by Lee. These medium-term results are important; however, more information is needed regarding the long-term safety and efficacy of DES.
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No studies were identified for other indications (DES restenosis, SVG stenosis, preventing stenosis in primary PTCA or preventing restenosis in femoropopliteal arteries).

2009 Update

Treating restenosis of bare-metal stents in native coronary arteries:
Holmes et al reported on a 3-year follow-up of one of the major clinical trials comparing brachytherapy to DES. In the principal publication of this trial reporting 9-month outcomes, DES decreased target lesion revascularization and angiographic restenosis. The 3-year results are that DES versus brachytherapy has greater survival free from target lesion revascularization (81% versus 71.6%, respectively), and greater survival free from target vessel revascularization (78.2% versus 68.8%, respectively). Deaths and MI were slightly higher in the DES group, but not statistically significantly different; however, the studies were not powered for these endpoints.

Treating restenosis in drug-eluting stents:
Only case series of patients had been reported before. Bonello et al. reported another case series of 99 patients with restenosis in DES treated with brachytherapy. In this series, at 12 months the target lesion revascularization rate was 11% and the MACE rate was 26%. Such case series data cannot determine whether brachytherapy is as or more effective than other methods of treating these restenoses.

In-stent restenosis in SVGs:
Mishra et al reported a retrospective comparison of patients with stenosis in SVG stents treated with DES or brachytherapy. Outcomes were reported at six months. DES-treated patients had lower rates of non-Q-wave MI than brachytherapy patients (0% versus 20%, respectively). Target lesion revascularization or MACE were lower but not statistically significantly different in the DES group than the brachytherapy group (21% versus 3%, p=0.13). The pattern of results for other outcomes suggests that DES is at least equivalent to brachytherapy and rates of outcomes are better (although not statistically significant in most cases).

Treating restenosis after treatment of peripheral vascular lesions:
No studies were found relevant to this indication.

In summary, the additional studies seem to be indicating at least equivalence, if not superiority, of DES in treating restenosis of stents, whether they are bare metal stents, DES or saphenous vein stents. At this time, no changes are being made to the existing vascular brachytherapy coverage statements.

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2. Blue Cross and Blue Shield Association: Intracoronary Brachytherapy as an Adjunct to Percutaneous Revascularization to Prevent and Manage Restenosis. TEC Assessment, 2000, Tab 19.

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Policy History

Original Effective Date: 01/27/2003
11/21/2002 Medical Policy Committee review
01/27/2003 Managed Care Advisory Council approval
01/26/2004 Managed Care Advisory Council approval
01/04/2005 Medical Director review. Name of policy changed from Intracoronary Brachytherapy for Management and Prevention of Restenosis following Percutaneous Transluminal Coronary Angioplasty (PTCA) to Intra-arterial Brachytherapy for Prevention and Management of Restenosis after Percutaneous Transluminal Angioplasty (PTA). Format revision. Coverage eligibility unchanged.
01/18/2005 Medical Policy Committee review
01/31/2005 Managed Care Advisory Council approval
02/01/2006 Medical Director review
02/15/2006 Medical Policy Committee review. Format revisions, Rationale updated based on literature review.
02/23/2006 Quality Care Advisory Council approval
07/07/2006 Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
02/07/2007 Medical Director review
02/21/2007 Medical Policy Committee approval. Policy name changed from “Intracoronary Brachytherapy for the Management and Treatment of Restenosis after Percutaneous Transluminal Angioplasty
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(PTA)” to “Intra-arterial Brachytherapy for the Management and Treatment of Restenosis after Percutaneous Transluminal Angioplasty (PTA)” Coverage eligibility unchanged.

02/13/2008 Medical Director review
02/20/2008 Medical Policy Committee approval
02/04/2009 Medical Director review
02/19/2009 Medical Policy Committee approval. No change to coverage eligibility.
02/04/2010 Medical Policy Committee approval
02/17/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/03/2011 Medical Policy Committee review
02/16/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2012 Medical Policy Committee review. Recommend archiving policy.
02/15/2012 Medical Policy Implementation Committee approval. Archived

Next Scheduled Review Date: Archived medical policy.

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

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A. in accordance with nationally accepted standards of medical practice;

B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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