Intravascular Brachytherapy after Percutaneous Transluminal Angioplasty

Type:  
Medical Necessity and Investigational / Experimental

Policy Specific Section:  
Radiology (Diagnostic/Therapeutic)

Original Policy Date:  
December 5, 2008

Effective Date:  
January 30, 2015

Definitions of Decision Determinations

Medically Necessary:  A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental:  A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation:  Blue Shield policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Treatment of narrowed and obstructed atherosclerotic arteries may be accomplished by bypassing the blockage using a graft, percutaneous transluminal angioplasty (balloon dilation of the blockage), and/or stents to hold the vessel open. However, these treatments are limited by high failure rates of restenosis within a year.
Intravascular brachytherapy was introduced as a method to treat in-stent restenosis by delivering a controlled dose of gamma or beta radiation to a target arterial lesion or bypass graft following angioplasty or stent surgery. It is proposed radiation delivered to the affected vessel via a catheter-based system reduces the intimal hyperplasia and inhibits negative vessel remodeling, each a cause of restenosis.

Intravascular brachytherapy in conjunction with percutaneous transluminal angioplasty has been investigated primarily in the coronary arteries, but also in the femoropopliteal system.

**Policy**

Intravascular coronary brachytherapy, as an adjunct to percutaneous transluminal angioplasty, may be considered **medically necessary** to treat either of the following:
- Restenosis of a previously placed bare-metal stent in the native coronary artery
- In-stent restenosis of a saphenous vein graft

Intravascular coronary brachytherapy is considered **investigational** for any other indication, including:
- Primary prevention of restenosis for de novo lesions, in conjunction with percutaneous transluminal angioplasty with or without stent placement
- Treatment or prevention of restenosis in a drug-eluting stent

Intravascular non-coronary brachytherapy is considered **investigational** for any indication including, but not limited to, the treatment or prevention of stenosis or restenosis in the femoropopliteal system.

**Internal Information**

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

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The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

APPENDIX to Intravascular Brachytherapy after Percutaneous Transluminal Angioplasty Policy

Prior Authorization Requirements

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Intracoronary Brachytherapy

The major limitation to the long-term success of percutaneous coronary interventions (PCIs), formerly known as percutaneous transluminal coronary angioplasties (PTCAs), is restenosis. The majority of PCIs performed in the United States include stent placement. However, even with stent placement, the restenosis rate (i.e., in-stent restenosis) occurs in 3% to 20% of patients (Dangas et al., 2010). Management of in-stent restenosis is notoriously ineffective, with moderate to high recurrence rates. Management has included PTCA alone, restenting, laser
angioplasty, and rotational atherectomy. These therapies, however, are often ineffective, requiring medical management or surgical revascularization.

Prior to the availability of drug-eluting stents (DES), the greatest amount of clinical experience in treating in-stent restenosis was with intravascular brachytherapy (IVB) in the coronary artery system, referred to as intracoronary brachytherapy (ICB), or intravascular coronary brachytherapy. In this radiation technique, a delivery catheter is placed in the coronary artery at the site of in-stent restenosis and a transfer device is connected to the catheter, delivering the radioactive seeds to administer radiation to the artery. After a specified period of time, the radioactive seeds are returned to the transfer device and removed.

The United States Food and Drug Administration (FDA) approved two beta radiation delivery devices for use in ICB: the Beta-Cath™ Intravascular Brachytherapy System (Best Vascular Inc., Norcross, GA), formerly known as the Novoste™ Beta-Cath™ system, and the GALILEO™ Intravascular Radiotherapy System (Guidant Corp., Houston, TX). The Cordis Checkmate™ System (Cordis Corp., Miami, FL) delivered gamma radiation. As of May 2007, the CheckMate™ and GALILEO™ systems and devices for IVB are no longer available, having been discontinued by their respective manufacturers. The FDA premarket approval limits the use of the Beta-Cath™ system to delivery of beta radiation at “the site of successful percutaneous coronary intervention” for the “treatment of in-stent restenosis in native coronary arteries with discrete lesions.”

The following describes the clinical applications of ICB in conjunction with percutaneous transluminal angioplasty (PTA) in the coronary arteries that have been investigated.

Management of In-Stent Restenosis in the Native Coronary Vessels and Saphenous Vein Grafts

Native Coronary Vessels

A 2000 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment based on four well-designed randomized clinical trials evaluated the effectiveness of brachytherapy for managing in-stent restenosis in the native coronary vessels. The outcomes of these trials indicated patients with in-stent restenosis treated with brachytherapy did better than patients treated with PTCA alone or with PTCA and stenting. Angiographic data at six to nine months showed a significant reduction in the restenosis rate in brachytherapy patients. More importantly, patients receiving brachytherapy had a statistically significant reduction in target lesion revascularization rates.

Later studies reported the same conclusions as the 2000 TEC Assessment (Leon et al., 2001; Popma et al., 2002; Waksman et al., 2002; Waksman et al., 2004). The 2005 guidelines from the American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) advised brachytherapy could be considered a useful, safe and effective treatment for in-stent restenosis (Level of Evidence A) (Smith et al., 2005). No changes were made in the 2009 focused update (Kushner et al., 2009).

Long-term studies reported a particular concern regarding the incidence of late stent restenosis. Grise and colleagues (2002) reported on five 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 three and five years in the treatment group, compared to none in the control group. Meerkin et al., (2002) focused on two-year follow-up of 30 patients treated with intracoronary beta irradiation. Late failures occurred in seven of the 30 patients. To address these concerns, the ACC/AHA/SCAI guidelines additionally recommended the following to reduce the risk of late stent thrombosis:

- New stents should not be implanted at the time of brachytherapy unless necessary
- Antiplatelet therapy with both aspirin and a thienopyridine should be continued for at least six to 12 months after brachytherapy (Waksman et al., 2002)

The 2008 American College of Radiology Guideline for the performance of coronary vascular brachytherapy advised “coronary vascular brachytherapy is indicated for in-stent restenosis of either native coronary artery vessels or saphenous vein grafts... used as an adjunct after the recanalization procedure with angioplasty and, rarely, with repeat stenting.”

Oliver and colleagues (2008) conducted a meta-analysis gathering 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): relative risk (RR) = 0.58; 95% confidence interval (CI): 0.50 to 0.67; p < 0.001), restenosis (RR = 0.55; 95% CI: 0.48 to 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 six to 24 months). Only five trials reported long-term outcomes (> 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.

Saphenous Vein Grafts

Waksman et al., (2002) reported results of a trial on the effects of intracoronary gamma brachytherapy in 120 patients with in-stent restenosis of saphenous vein grafts. Restenosis rates were lower in the 60 patients assigned to gamma brachytherapy compared to the 60 patients assigned to placebo (21% versus 44%, p = 0.005). The rate of revascularization of the target lesion at 12 months was 70% lower in the gamma brachytherapy group than the placebo group (17% versus 57%, p < 0.001). Major cardiac events were 49% lower (32% versus 63%, p < 0.001). The authors concluded there was adequate support for the use of brachytherapy in the treatment of in-stent restenosis in patients with bypass grafts.

Castagna et al., (2002) reported on the six-month follow-up of 45 of 120 patients in the Washington Radiation for In-Stent Restenosis Trial for Saphenous Vein Grafts (SVG-WRIST) with restenotic lesions of saphenous vein grafts who were evaluated by intravascular ultrasound. The investigators reported a significant reduction in repeat stenosis in the patients randomized to gamma brachytherapy compared to placebo. Additionally, the effectiveness of gamma brachytherapy in patients with restenosis of saphenous vein grafts was similar to that reported in other trials of gamma radiation therapy in patients with restenosis of native coronary lesions. The investigators concluded IVB effectively reduced intimal hyperplasia reaccumulation in vein graft in-stent restenosis with no deleterious effect on reference segments within six months.
Rha and colleagues (2005) published follow-up of the SVG-WRIST trial to determine whether the safety and efficacy of brachytherapy was durable. The authors concluded patients in the SVG-WRIST trial treated with brachytherapy had a marked reduction in the need for repeat target lesion revascularization at 36 months and sustained clinical benefit at three years despite late recurrences that were more pronounced in the irradiated group.

Currently, gamma radiation sources for IVB are not marketed in the United States, and it is unlikely IVB is commonly performed in this country for the treatment of in-stent restenosis of saphenous vein grafts.

Presently, DES are now the stents of choice for most coronary interventions. Additionally, studies have indicated equivalence, if not superiority, of DES in treating restenosis of stents, whether they are bare-metal stents, drug-eluting stents, or saphenous vein stents (Pohl et al., 2005; Mishra et al., 2006; Stone et al., 2006; Holmes et al., 2006; Torguson et al., 2006; Schukro et al., 2007; Holmes et al., 2008; Park et al., 2008; Ellis et al., 2008). Due to the increased efficacy of DES for in-stent restenosis, the role of intracoronary radiation for in-stent restenosis has decreased and the future role in the treatment of in-stent restenosis is uncertain.

**Primary Prevention of De Novo Restenosis With or Without Stent Placement**

Intracoronary brachytherapy has been investigated both as an alternative to stent placement to reduce the risk of de novo restenosis and as an adjunctive technique at the time of intracoronary stent placement to reduce the risk of in-stent restenosis. These applications of ICB are off-label indications.

Data are limited on the routine use of ICB after angioplasty alone, as a prophylactic measure to prevent restenosis. Since the majority of PCIs currently performed included stent placement, this issue has become less significant. Small case series and a small clinical trial, suggested a reduction in postangiography restenosis with ICB, using either a gamma or beta-emitter (Condado et al., 1997; King et al., 1998; Raizner et al., 2000). However, a larger study of 1455 patients with either a single de novo lesion or unstented restenosis found no significant decline in clinical restenosis with radiotherapy with a beta-emitter compared to placebo (Serruys, 2001). The authors reported although ICB reduced the incidence of angiographic restenosis within the lesion segment, it increased restenosis at the lesion edges.

The 2000 TEC assessment concluded there were no RCTs supporting the use of ICB for the prevention of restenosis. Serruys and colleagues (2004) reported on the results of a randomized trial of ICB as primary prevention for de novo coronary artery lesions treated with stenting. Of 112 patients, 54 were randomly assigned to radiation after stent placement. At six months, minimal lumen diameter was significantly greater and volume loss was significantly less with ICB. However, despite efforts to optimize procedural performance, edge restenosis and late occlusions resulted in a higher rate of target vessel revascularization with radiation (20% versus 12%). The authors reported the clinical outcomes of the irradiated group were inferior to those of the non-irradiated control group.

Five studies reported on use of ICB to prevent restenosis after primary percutaneous interventions, including three with long-term (3.8 to five years) follow-up (Gruberg et al., 2006; Ferrero et al., 2007; Nikas et al., 2007) and two with intermediate-term (nine to 16 months)
follow-up (Syeda et al., 2006; Geiger et al., 2006). The studies with long-term follow-up reported early benefit from ICB 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 (Nikas et al., 2007).

Intravascular brachytherapy has also been investigated as a first-line treatment of stenosis, however clinical trials suggested ICB was associated with inferior outcomes compared to angioplasty and stenting alone (Serruys et al., 2004).

Ho and colleagues (2011) evaluated the long-term clinical outcomes of 129 patients after administration of IVB for in-stent restenosis and de novo coronary artery lesions in PCI. The majority of patients had diffuse bare-metal in-stent restenotic lesions and 19 patients (15%) had de novo coronary artery lesions. The patients were followed from hospital discharge to follow-up at five years. The authors reported MACE rates remained high post IVB at five years of follow-up and were mainly driven by the need target lesion revascularization. Left anterior descending artery as a target vessel of PCI was an independent predictor of long-term MACE.

The FDA labeling for ICB is limited to its use as a treatment of in-stent restenosis, and its use for primary prevention of de novo restenosis with or without stent placement, or first-line treatment of stenosis, remains investigational.

Treatment of Restenosis of Drug-Eluting Stents

When cardiologists find restenosis after implanting a DES, they often place a stent that elutes a different drug within the stent. If a patient presents with restenosis in the segment that has already been treated with both sirolimus and paclitaxel-DES, further options are limited. Intracoronary brachytherapy has been used in this scenario; however the efficacy of this approach has not been well studied.

Two clinical series reported on use of IVB to treat restenosis in a DES. In one series, Torguson and colleagues (2006) 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% versus 2.4%; p = 0.044). Price et al., (2007) reported on the second series which only included five patients, all with recurrent stenosis after sequential treatment with sirolimus- and paclitaxel-DES.

Bonello et al., (2008) 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 and further study is needed.

Intravascular Brachytherapy of the Femoropopliteal System

Intravascular brachytherapy has also been investigated in conjunction with PTA of the femoropopliteal systems, as a technique to reduce the risk of a de novo restenosis, either in native or grafted vessels, with or without stent placement. 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.

A 2002 TEC Assessment offered the following observations and conclusions regarding intravascular femoropopliteal radiation therapy:

- The scientific evidence consisted of two randomized trials comparing PTA plus brachytherapy with angioplasty alone (Minar et al., 2000; Polrajac et al., 2000; Krueger et al., 2002). Both trials had limitations that precluded conclusions on whether brachytherapy was efficacious for the population under consideration. The Vienna-2 trial (Minar et al., 2000) 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 evidence was insufficient to permit scientific conclusions regarding brachytherapy as an adjunct to peripheral artery angioplasty

Bonvini and colleagues (2003) 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 (2005) 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, 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 six- and 12-month follow-up between the two groups (33% with brachytherapy versus 35% without at six months; and 59% with brachytherapy versus 43% without at 12 months) (Wolfram et al., 2005).

Two studies reported long-term follow-up after endovascular brachytherapy to prevent restenosis in femoropopliteal arteries treated with balloon angioplasty (Diehm et al., 2005; Wolfram et al., 2006). Both reported 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 ACC/AHA Guidelines for the Management of Patients with Peripheral Artery Disease (Hirsch et al., 2006) stated investigational randomized trials suggested endovascular
brachytherapy may reduce restenosis rates of PTA and stenting in the femoral-popliteal arteries however, their recommendations did not include brachytherapy for the treatment of peripheral artery disease in the lower extremity.

In a German systematic review, Gorenoi and colleagues (2009) evaluated the medical efficacy and cost-effectiveness of IVB in peripheral arterial occlusive disease patients. Twelve publications covering seven studies on IVB versus no IVB were included in the evaluation. Intravascular brachytherapy after successful PTA showed a significant reduction in the rate of restenosis at six and/or 12 months and a significant delay in the time of recurrence of restenosis. Intravascular brachytherapy after stenting did not lead to significant results regarding the restenosis rates, but was more often associated with early and late occlusive thromboses. The authors concluded IVB after successful PTA could be recommended from a medical point of view; however from the health economic perspective the answer was not yet clear. Intravascular brachytherapy after stenting could not be recommended.

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

In summary, the clinical efficacy of ICB using gamma or beta radiation for the management of coronary in-stent stenosis has been established. However, the increased efficacy of DES for in-stent restenosis has markedly limited the role of intracoronary radiation for use in the treatment of in-stent restenosis. Current data do not support the use of intracoronary radiation for the prevention of restenosis of de novo lesions or DES, as well as the treatment of restenosis of DES. Additionally, the FDA has not approved ICB for these indications. The safety and efficacy of IVB for the treatment or prevention of stenosis or restenosis of the femoropopliteal arteries has not been established. Further, there are no FDA-approved devices for IVB of the femoropopliteal system.

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

*This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy*
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**Tables**

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Definitions

**Bypass graft** - A piece of a blood vessel, typically from the leg (saphenous vein), an artery on the chest wall (internal mammary), or radial artery graft, used during heart surgery to bypass a blockage in a native coronary artery.

**De novo** - Newly developed, not previously present; in this instance de novo refers to new stenotic lesions.

**Native coronary artery** - The arteries in the heart that a person is born with, which supply blood to the heart muscle.

**Percutaneous transluminal angioplasty (PTA)** - A procedure for enlarging a narrowed vascular lumen by inflating and withdrawing through the stenotic region with a balloon on the tip of an angiographic catheter; may include positioning of an intravascular endoluminal stent.

**Restenosis** - A recurrence of narrowing or constriction in a blood vessel.

**Stenosis** - A constriction or narrowing of a blood vessel (initial).

**Stent** - A wire mesh tube-like device used to prop open an artery that has recently been cleared using angioplasty; this type of device stays in the artery permanently, holds it open, and improves blood flow to the heart muscle.

- **Bare-metal stent** - A vascular stent without a coating.
- **Drug-eluting stent** - A coated coronary stent that slowly releases a drug to block cell proliferation.

**Target lesion revascularization** - A rate measuring how many stented lesions had to be retreated due to clinically-driven restenosis in a specific time period.

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Brachytherapy for Oncologic Indications

Key / Related Searchable Words

- Brachytherapy, Intracoronary Arteries
- Intra-arterial Radiation Therapy
- Intracoronary Radiation Therapy
- Vascular Brachytherapy
References

- Blue Cross Blue Shield Association. Technology Evaluation Center (TEC) Assessment: Brachytherapy for the prevention of restenosis in peripheral arteries following a percutaneous transluminal angioplasty (PTA) of the femoropopliteal system. 2002; Tab 22.


- Serruys PW. Arterial Revasularization Therapy Study. Presented at the American College of Cardiology 50th Annual Scientific Sessions 2001; Orlando, Florida.

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy