Anthem

Clinical UM Guideline

Subject: Intravascular Brachytherapy (Coronary and Non-Coronary)
Guideline #: CG-THER-RAD-07
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Description

This document addresses the use of intravascular brachytherapy for treatment of vascular disease. This document does not address the use of intravascular brachytherapy to treat oncologic conditions.

Clinical Indications

Medically Necessary:

Intravascular coronary brachytherapy, also called intracoronary brachytherapy, is considered **medically necessary** as a treatment of in-stent restenosis.

Not Medically Necessary:

Intravascular coronary brachytherapy is considered **not medically necessary** for all other uses not specified above as medically necessary, including, but not limited to, the following:

- As an initial treatment of coronary artery disease to prevent de novo stenosis either within or adjacent to stent placement
- Repeat intracoronary brachytherapy

Non-coronary intravascular brachytherapy is considered **not medically necessary** for the treatment or prevention of stenosis or restenosis in blood vessels, including, but not limited to, the femoropopliteal vessels.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

Intravascular Coronary Brachytherapy
When services may be Medically Necessary when criteria are met:

CPT

77770	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel [when specified as coronary intravascular brachytherapy]
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels [when specified as coronary intravascular brachytherapy]
77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels [when specified as coronary intravascular brachytherapy]
92974	Transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy

HCPCS

C7533	Percutaneous transluminal coronary angioplasty, single major coronary artery or branch with transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy

ICD-10 Procedure

02700T6-02734TZ	Dilation of coronary artery, with radioactive intraluminal device [by number of arteries and approach; includes codes 02700T6, 02700TZ, 02703T6, 02703TZ, 02704T6, 02704TZ, 02710T6, 02710TZ, 02713T6, 02713TZ, 02714T6, 02714TZ, 02720T6, 02720TZ, 02723T6, 02723TZ, 02724T6, 02724TZ, 02730T6, 02730TZ, 02733T6, 02733TZ, 02734T6, 02734TZ]

ICD-10 Diagnosis

T82.855A-T82.855S	Stenosis of coronary artery stent

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for the diagnoses listed below, or for situations designated in the Clinical Indications section as not medically necessary.

ICD-10 Diagnosis

I25.10-I25.9	Chronic ischemic heart disease

Non-coronary Intravascular Brachytherapy
When services are Not Medically Necessary:
For the following procedure and diagnosis codes; or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

CPT

77770	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel [when specified as non-coronary intravascular brachytherapy]
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels [when specified as non-coronary intravascular brachytherapy
77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels [when specified as non-coronary intravascular brachytherapy]
93799	Unlisted cardiovascular service or procedure [when specified as transcatheter placement of radiation delivery device for non-coronary intravascular brachytherapy]

ICD-10 Diagnosis

I70.0-I70.92	Atherosclerosis
T82.856A-T82.856S	Stenosis of peripheral vascular stent

Discussion/General Information

Intravascular brachytherapy (IVB) refers to the application of radiation (using gamma or beta radiation) directly to the site of a vessel narrowing. This involves the temporary placement of radioactive substances, usually in the form of a thin catheter filled with radioactive seeds, a radioactive wire, or a balloon coated or filled with radioactive material, to treat stenosis which occurs at the site of a prior stent (in-stent restenosis).

When used to treat lesions in the coronary arteries, IVB may also be referred to as intravascular coronary brachytherapy (ICB). Radiation reduces the proliferation of the vessel's smooth muscle cells, preventing or delaying long-term occurrence of restenosis.

Intravascular Coronary Brachytherapy
There are well-designed, randomized, clinical trials evaluating the effectiveness of brachytherapy using gamma or beta radiation for the management of coronary in-stent restenosis. These trials report that individuals receiving brachytherapy have statistically significant reductions in restenosis and in target lesion revascularization rates (Leon, 2001; Popma, 2002; Waksman, 2002a; Waksman, 2002b; Waksman, 2003). Long-term studies, however, have reported late occurrences of restenosis (Grise, 2002; Maeder, 2008; Meerkin, 2002; Silber, 2005). While there was initial interest in IVB as a first-line treatment of stenoses, evidence from other clinical trials suggests that drug-eluting stents (DES) may be more effective in preventing in-stent restenosis (Ellis, 2008; Oliver, 2008; Park, 2008). Restenosis following bare-metal stent implantation is not uncommon (Holmes, 2008). Clinical trials show that the treatment of restenosis with drug-eluting stents after implantation of bare-metal stents results in better clinical outcomes such as improved event-free survival and reduced angiographic restenosis (Stone, 2006; Holmes, 2006).

Lu (2011) conducted a meta-analysis to compare the outcomes of DES versus IVB for in-stent restenosis. Twelve studies met study criteria and were reviewed; four trials were randomized and eight were nonrandomized. The mid-term follow-up period was 6 to 12 months. Target-vessel revascularization data showed that the occurrence of target-vessel revascularization was significantly reduced by the use of DES (odds ratio 0.45%). A subgroup analysis showed a difference in the result between the randomized trials and nonrandomized trials. Randomized trials showed greater benefit with DES whereas the nonrandomized trials showed no difference between DES and IVB. At mid-term follow-up, binary restenosis was found to have occurred in 13.9% of individuals treated with DES and in 29.5% of those individuals treated with IVB. At the mid-term follow-up period, late lumen loss showed no significant effect of the use of DES in the randomized trials, but showed a significant reduction in the non-randomized trials. During the mid-term follow-up period, no differences were noted between DES and IVB in cardiac death, myocardial infarction and late stent restenosis. A long-term follow-up period of 24 to 36 months was recorded for target-vessel revascularization, cardiac death and myocardial infarction (insufficient data was provided to perform long-term follow-up analysis for binary stenosis and late lumen loss). A significant difference was found for target-vessel revascularization (odds ratio: 0.61, 95% confidence interval [CI]: 0.43-0.86, P=0.005). There were no significant differences found between DES versus IVB for cardiac death and myocardial infarction. These findings suggest that the use of DES for in-stent restenosis when compared with IVB appears to be associated with reduced occurrences of target-vessel revascularization and binary restenosis, there may be a possible benefit from DES in late lumen loss reduction, but DES were not superior to IVB in reducing death or myocardial infarction.

In a 2018 retrospective review by Varghese and colleagues, 197 participants with recurrent DES in-stent restenosis underwent treatment with IVB compared to 131 participants who underwent routine percutaneous intervention (non-IVB group). The primary end point was major adverse cardiac events (MACE) which was defined as a composite of target lesion revascularization, myocardial infarction, and all-cause mortality at 12 months. For all 328 participants treated for recurrent DES restenosis, immediate angiographic success was achieved and participants were discharged alive from the hospital. For those participants who underwent IVB there were no immediate periprocedural complications attributed to the use of the brachytherapy catheter. At 12 months, the MACE rates were lower in the IVB arm when compared to the non-IVB group (13.2% and 28.2%; p=0.01). Target lesion revascularization rates were lower in the IVB arm compared to the non-IVB group (17.8% and 29%; p=0.09). At the 12-month analysis, there were no significant differences between the groups noted in either death, myocardial infarction or stent thrombosis. The participants in this study represent a high-risk group for restenosis given their high prevalence of clinical risk factors. Limitations to this study include its retrospective nature and a relatively short follow-up time of 12 months. Longer-term follow-up is needed to rule out concerns such as the late catch-up phenomenon and very late stent thrombosis. Even with the limitations, this study shows benefit of IVB by reducing restenosis and short-term MACE.

Another retrospective study by Nakahama and colleagues (2018) reports the 10-year results of MACE in 680 participants treated with IVB for coronary in-stent restenosis. MACE was defined as all-cause death, myocardial infarction, and target vessel revascularization. At 10-year follow-up, the rate of death was 25%, myocardial infarction was 22.4%, and target vessel revascularization was 48%. This study's retrospective design precludes conclusions about cause and effect. Its single center design limits generalizability to different practice settings. The absence of standardized follow-up after IVB confounds understanding of whether the IVB was responsible for the observed results. However, the results appear to be similar with other studies which shows benefit for IVB for coronary in-stent restenosis.

A systematic review and meta-analysis (Megaly and colleagues, 2020) reported on long-term outcomes of IVB in recurrent in-stent restenosis. The five observational studies included 917 participants. The primary outcome was target vessel revascularization with secondary outcomes including myocardial infarction and all-cause mortality. At 1 year after IVB, the incidence of target vessel revascularization was 17.5%. Myocardial infarction occurred in 3.1%. At 2 years after IVB, the incidence of target vessel revascularization was 26.7% and the incidence of myocardial infarction was 3.9%. With a mean follow-up time of 24 ± 7 months, incidence of target vessel revascularization was 29.2%, incidence of myocardial infarction was 4.3%, and incidence of all-cause mortality was 7.3%. While the observational, single-arm design without a control group does not permit conclusions about cause and

effect, the study shows that IVB is associated with favorable outcomes as a treatment for in-stent restenosis.

In a 2021 retrospective review, Yerasi and colleagues evaluated optimal treatment for individuals with recurrent in-stent restenosis after an initial failed IVB. The primary end point was MACE rate 3 years following treatment. There were 279 participants who underwent percutaneous coronary intervention after the initial failed IVB. Standard treatment consisting of balloon angioplasty with or without DES was performed on 215 participants. Another 64 participants underwent balloon angioplasty followed by repeat IVB. There were no differences in MACE rates between the two treatment groups at 30 days and at 6 months following treatment. At 1 year, MACE rate for the standard treatment group was 30.9% and 14% in the repeat IVB group. At 2 years, MACE rate was 50.7% in the standard treatment group and 30.6% in the repeat IVB group. At 3 years, MACE rate was 57.3% in the standard treatment group and 40.6% in the repeat IVB group. While the study showed potential benefit of repeat IVB, limitations to the study include the retrospective design, possible selection bias, and the high percentage of participants lost to follow-up (37% at 3 years). Additionally, not all participants received follow-up angiogram and the cohort wasn't large enough to compare all possible treatment modalities (DES, atherectomy, etc.). There is also concern regarding cumulative radiation dose related to repeat IVB and the lack of healing of the metallic stent with repeat radiation. Further, prospective studies should be done to evaluate all optimal treatment strategies before considering repeat IVB.

Two recently published literature reviews (Detloff, 2022; Mittal, 2022) reported IVB to be effective as a treatment option for those with in-stent restenosis who are not candidates for repeat DES treatment.

A 2023 retrospective study by Salihu and colleagues reported on the long-term clinical outcome of individuals treated with intracoronary brachytherapy. Primary endpoint was all-cause mortality. There were 173 participants who had intracoronary brachytherapy for in-stent restenosis. Survival follow-up data was available for 166 individuals. Mean follow-up was 20 years. There were 110 participants (66%) who died during follow-up with death considered to be cardiac in origin in 74 of those participants (67%). The cumulative survival rate at 1, 5, 10, 15, and 20 years was 90%, 78%, 59%, 43%, and 34%, respectively. The cumulative MACE-free rate at 1, 5, 10, 15, and 20 years was 77%, 54%, 29%, 14%, and 4%, respectively. This study has limitations including the retrospective design and number of participants lost to follow-up. Those who undergo ICB warrant regular clinical follow-up.

The American College of Cardiology (ACC)/American Heart Association (AHA)/Society for Cardiovascular Angiography and Interventions in their 2021 Guideline for Coronary Artery Revascularization, note that lower rates of restenosis occur with the use of DES when compared to bare-metal stents or vascular brachytherapy. They also note for individuals who have multiple stent layers or recurrent in-stent restenosis with an artery not amenable to another DES or bypass surgery, vascular brachytherapy can assist revascularization.

Intravascular Non-coronary Brachytherapy
IVB has also been studied as an adjunct to percutaneous transluminal angioplasty of the femoropopliteal system. While the greatest amount of clinical experience with IVB is in the coronary artery system, there are a number of important differences that preclude extrapolation of results from the coronary to the peripheral arterial system. There is greater anatomic variability in length, diameter, thickness, curvature, and orientation for peripheral arteries than for coronary arteries. The larger size of peripheral arteries requires treatment with a high-energy gamma radiation source rather than the beta radiation that is more commonly used for the coronary arteries. Gamma radiation sources for IVB are not currently marketed in the United States.

Studies have focused on IVB as an adjunct to primary angioplasty or as a treatment of restenosis. One randomized trial enrolled 113 individuals with either de novo or restenotic lesions of the femoropopliteal system. Participants underwent angioplasty with or without IVB (Wolfram, 2005). At 6-month follow-up, the restenosis rate was lower in the IVB group compared to the angioplasty group. However, by 5-year follow-up, there were no differences in the stenosis rate between the two groups. Diehm and colleagues (2005) reported on the results of a similarly designed trial enrolling 147 individuals. These authors also reported that the short-term improvements in restenoses associated with IVB were not maintained in the longer term.

Mitchell et al (2012) reported on a literature review and meta-analysis of randomized clinical trials for brachytherapy and restenosis following lower limb angioplasty. Six trials were identified (687 participants). All six trials reported 12-month data with respect to restenosis; 99/343 brachytherapy participants had restenosis at 12 months versus 147/344 control participants with restenosis at 12 months (pooled odds ratio 0.50; 95% CI, 0.301-0.836; p=0.008). At 24 months, three trials reported data regarding restenosis; 43/154 brachytherapy participants had restenosis versus 82/157 controls (pooled odds ratio 0.32; 95% CI, 0.02-1.621; p=0.17). Rates for re-intervention within 12 months were reported by four trials; 25/166 required re-intervention versus 41/171 controls (pooled odds ratio 0.53; 95% CI, 0.272-1.017; p=0.06). Three trials reported the development of new stenosis in the irradiated artery within the first year, but it was outside the previously irradiated area (16/109 brachytherapy participants versus 3/115 controls; pooled odds ratio 8.65; 95% CI, 2.176-34.391; p=0.002). While it is suggested there is some early benefit of brachytherapy, there is an increased risk of new lesions developing and there is a lack of long-term reductions in risk.

The American College of Cardiology Foundation (ACCF)/AHA guideline for the management of patients with peripheral artery disease (Gerhard-Herman 2016) does not include any recommendations for IVB of the femoropopliteal system.

The Society for Cardiac Angiography and Interventions consensus guidelines for device selection in femoral-popliteal arterial interventions (Feldman, 2018) does not recommend brachytherapy for femoropopliteal revascularization due to lack of supportive data or failure to demonstrate significant advantages over currently available percutaneous transluminal angioplasty or stents.

Definitions

De novo: Something that is newly developed or was not previously present. In the context of this document, de novo refers to new stenotic lesions either in previously untreated vessels or vessels that have received prior ICB but at a new location adjacent to the existing lesion.

Intravascular brachytherapy: A type of medical therapy that involves the placement of a radioactive substance at the site of a previously cleared blood vessel. This therapy is intended to treat recurrences of vessel blockages.

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

Restenosis: A recurrence of narrowing or constriction.

Stenosis: A constriction or narrowing of a passage.

Stent: A wire mesh tube-like device used to prop open an artery after initial angioplasty.

References

Peer Reviewed Publications:

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2. Diehm N, Silvestro A, Do DD et al. Endovascular brachytherapy after femoropopliteal balloon angioplasty fails to show robust clinical benefit over time. J Endovasc Ther. 2005; 12(6):723-730.
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Government Agency, Medical Society, and Other Authoritative Publications:

1. Feldman DN, Armstrong EJ, Aronow HD, et al. SCAI consensus guidelines for device selection in femoral-popliteal arterial interventions. Catheter Cardiovasc Interv. 2018; 92(1):124-140.
2. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the management of patients with lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2016: S0735-1097(16)36902-9.
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Websites for Additional Information

1. The American Heart Association. Available at: https://www.heart.org/. Accessed on September 20, 2023

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Brachytherapy, Intravascular Coronary
Brachytherapy, Intravascular Non-Coronary
Novoste™ Beta-Cath™ System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information and References sections.
Reviewed	11/10/2022	MPTAC review. Updated Discussion/General Information and References sections. Updated Coding section with 01/01/2023 HCPCS updates; added C7533.
Reviewed	11/11/2021	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	11/05/2020	MPTAC review. Updated Discussion/General Information and References sections. Reformatted Coding section; clarified applicable diagnosis codes.
Reviewed	11/07/2019	MPTAC review.
Reviewed	01/24/2019	MPTAC review. Updated Discussion/General Information and References sections.
New	03/22/2018	MPTAC review. Initial document development. Moved content of THER-RAD.00003 Intravascular Brachytherapy (Coronary and Non-Coronary) to new clinical utilization management guideline document with the same title.
