Peripheral Atherectomy and Thrombectomy Devices

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers mechanical or laser peripheral atherectomy (atheroablation) medically necessary in members who meet all of the following criteria:

I. Member has symptomatic infrainguinal atherosclerotic arterial occlusive disease caused by atherosclerosis involving the femoral, popliteal, and/or infrapopliteal arteries (limb-threatening ischemia or functionally limiting claudication); and

II. Member can not be treated by standard angioplasty techniques alone, (i.e., balloon angioplasty, etc.); and

III. Either A or B:

A. Member has an eccentric lesion that does not dilate with conventional balloon angioplasty, or

B. Member has vein bypass graft stenosis.

Policy History

Last Review 03/09/2017
Effective: 10/13/1998
Next Review: 03/08/2018

Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
Aetna considers mechanical or laser peripheral atherectomy experimental and investigational for all other indications, including peripheral atherectomy of the renal artery, visceral artery, abdominal aorta, brachiocephalic trunk and branches, and iliac artery, because its effectiveness for these indications has not been established.

Aetna considers isolated segmental pharmacomechanical thrombolysis (Trellis Peripheral Infusion System) experimental and investigational for treatment of deep venous thromboses, Paget-Schroetter syndrome (also known as venous thoracic outlet syndrome) and other indications because there is inadequate evidence in the peer-reviewed published clinical literature regarding its effectiveness.

Aetna considers a drug-eluting balloon for mechanical or laser peripheral atherectomy experimental and investigational for the treatment of in-stent restenosis of peripheral arteries because there is inadequate evidence in the peer-reviewed published clinical literature regarding the effectiveness of this approach.

Aetna considers the use of drug-eluting balloons for in vein grafts and dialysis/vascular accesses, and for the treatment of primary lesion/occlusion of peripheral arteries experimental and investigational because its long-term effectiveness has not been established.

Notes:

The preferred technique for mechanical atherectomy involves the use of the Simpson Atherocath (directional atherectomy). Peripheral atherectomy/atheroablation with other mechanical or rotational devices or rotational aspiration atherectomy devices has not been shown to be effective.

Peripheral laser atherectomy is also known as peripheral laser angioplasty.

Background

Atherectomy was introduced in 1985 to improve upon the limitations of balloon angioplasty, primarily, abrupt reclosure and restenosis. Atherectomy devices cut and remove atherosclerotic plaque from a vessel wall or grind the atheroma into small
particles, allowing them to embolize distally. Elastic recoil is reduced after atherectomy because the lumen is widened without stretching of the arterial wall.

Several types of atherectomy devices have been cleared by the U.S. Food and Drug Administration for peripheral use and primary success rates have been favorable with various devices; however, the Simpson Peripheral Atherocath has been the most widely used. This device has a circular cutter that spins at 2,000 rpm inside a metal housing with a window. Balloon inflation on the opposite side of the housing forces the plaque through the window where it is cut by advancing the rotating cutter in the housing. This device is best suited for short, discrete, eccentric stenosis. The catheters are bulky and stiff to use in the tibial or tortuous vessels. Primary success rate have been 82 to 100 % with few complications.

Data support the use of atherectomy as effective in the peripheral vessels in patients who meet the following criteria: have symptomatic peripheral vascular disease (limb-threatening ischemia or functionally limiting claudication); and cannot be treated by standard angioplasty techniques alone, i.e., balloon angioplasty would be ineffective or is contraindicated; and have an eccentric lesion that does not dilate with conventional balloon angioplasty, or vein bypass graft stenosis.

Until the problem of restenosis can be solved, atherectomy is a reasonable treatment for symptomatic peripheral vascular disease (limb-threatening ischemia or functionally limiting claudication) only when balloon angioplasty may be ineffective or contraindicated.

Zeller et al (2007) reported a safety and efficacy study of the first rotational aspiration atherectomy system (Pathway PV) for the treatment of arterial lesions below the femoral bifurcation. A total of 15 patients (9 men; mean age of 71 +/- 9 years) with Rutherford stage 2 to 5 lower limb ischemia were enrolled at 3 study sites. Target lesions were in the superficial femoral (n = 7, 47 %), popliteal (n = 7, 47 %), and posterior tibial (n = 1, 6 %) arteries. Mean diameter stenosis was 97 % +/- 10 %; mean lesion length was 61 +/- 62 mm (range of 5 to 250). The primary study endpoint was the 30-day serious adverse event (SAE) rate.
Interventional success (residual stenosis less than 30%) was achieved in all lesions (100%). Stand-alone atherectomy was performed in 6 (40%) patients, adjunctive balloon angioplasty in 7 (47%), and stenting/endografting in 2 (13%). The SAE rate at 30 days was 20% (3/15), including 1 perforation due to an unrecognized displacement of the guidewire (sealed with an endograft), 1 false aneurysm at the puncture site (successful duplex-guided compression therapy), and 1 dissection in conjunction with a distal embolism (stent implantation and aspiration thrombectomy). Primary patency rates measured by duplex ultrasound at 1 and 6 months were 100% and 73%, respectively; the target lesion revascularization (TLR) rate was 0% after 6 months. The ankle-brachial index increased significantly from 0.54 +/- 0.3 at baseline to 0.89 +/- 0.16, 0.88 +/- 0.19, and 0.81 +/- 0.20 (p < 0.05) at discharge, 1 month, and 6 months, respectively. Mean Rutherford categories were 2.92 +/- 1.19 (range of 1 to 5), 0.64 +/- 1.12 (range of 0 to 1), and 0.83 +/- 1.33 (range of 0 to 3) at the same time points (p < 0.05). The authors concluded that the application of this new atherectomy device was feasible in all cases. The serious adverse event rate was moderate; however, all events were solved during the index procedure. The 0% 6-month TLR rate is promising.

Mahmud et al (2007) noted that over the past decade, percutaneous revascularization therapies for the treatment of patients with peripheral arterial disease (PAD) have evolved tremendously, and a great number of patients can now be offered treatment options that are less invasive than traditional surgical options. With the surgical approach, there is significant symptomatic improvement, but the associated morbidity and mortality preclude its routine use. Although newer percutaneous treatment options are associated with lower procedural complications, the technical advances have outpaced the evaluation of these treatments in adequately designed clinical studies, and therapeutic options are available that may not have been rigorously investigated.

Bunting and Garcia (2007) stated that atherectomy is experiencing increased interest from endovascular specialists as a therapeutic treatment in the peripheral arteries. Long studied in
the coronary vasculature, atherectomy has several theoretical advantages that make it uniquely suited for the peripheral circulation. In particular, infra-inguinal PAD experiences physiological stresses and forces that have made traditional percutaneous coronary treatments such as angioplasty and stenting not as successful. Re-stenosis has been a major problem for angioplasty and stenting alone. The SilverHawk atherectomy device has favorable short-term data but important longer-term data are limited and need further study. Laser atherectomy also has favorable applications in niche patients but the number of studies is limited. Unfortunately, athero-ablative technologies for PAD require more definitive objective data regarding 12-month and longer-term outcomes in order to obtain widespread scientific acceptance.

Biskup et al (2008) noted that a new atherectomy device (SilverHawk) has recently been approved by the Food and Drug Administration, but the results with its use are unclear. These investigators analyzed a series of consecutive patients undergoing atherectomy. They retrospectively reviewed the charts of 35 patients undergoing infra-inguinal (IF) atherectomy in 38 limbs. The Trans-Atlantic Inter-Society Consensus (TASC) classification and Society of Vascular Surgery run-off scores were calculated. Time to event analysis was performed using Kaplan-Meier estimates. Risk factors affecting patency were analyzed with a multi-variate Cox model. Mean patient age was 70 +/- 9.6 years. Indications for intervention were claudication (26 %), rest pain (21 %), and tissue loss (53 %). Femoro-popliteal (FP) atherectomy was performed in 68 % and tibial atherectomy in 32 %. For FP lesions, the TASC distribution was A, 42 %; B, 23 %; C, 4 %; and D, 15 %. The average lesion treatment length was 9.4 +/- 10.6 cm (range of 1 to 40), and the run-off score was 5.1 +/- 3.5. For tibial lesions, the TASC distribution was A, 0 %; B, 17 %; C, 8 %; and D, 75 %. The average lesion treatment length was 9.2 +/- 6.0 cm (range of 2 to 20), with a run-off score of 5.4 +/- 2.4. A total of 39 % of patients had prior IF interventions. Adjunctive angioplasty of the atherectomized lesion was performed in 55 % of cases, stenting in 0 %, and adjunctive therapy for tandem lesions in 39 %. The post-operative ankle-brachial index increased by 0.30 +/- 0.14 and toe pressures increased by 40 +/- 32.4 mm Hg. Mean
follow-up was 10 +/- 8 months (range of 0.3 to 23). During the studied period, 7 patients required major limb amputation and 5 open surgical re-vascularization. Total primary and secondary patency rates were 66 % and 70 % at 1 year, respectively. Primary and secondary patency rates for FP atherectomy were 68 % and 73 % at 1 year, respectively. The limb salvage rate was 74 % at 6 months. Patients with prior interventions in the atherectomized segment had an almost 10-fold decrease in primary patency. Atherectomy produces acceptable results, similar to those in reported series of conventional balloon angioplasty/stenting. Patients with prior IF interventions had a nearly 10-fold decrease in primary patency. A greater than 6-fold decrease in patency rates was noted in patients who underwent simultaneous inflow or outflow procedures, but this finding did not reach statistical significance (p = 0.082). The authors stated that future studies should focus on cost comparisons with other treatments such as angioplasty and stenting, and prospective randomized trials should be performed to compare these treatment alternatives.

Garcia and Lyden (2009) noted that compared to conventional percutaneous transluminal angioplasty (PTA) and stent implantation for arterial occlusive diseases, atherectomy offers the theoretical advantages of eliminating stretch injury on arterial walls and reducing the, rate of restenosis. Historically, however, neither rotational nor directional atherectomy, whether used alone or with adjunctive PTA, has shown any significant long-term benefit over PTA alone in the coronary or peripheral arteries. However, the SilverHawk Plaque Excision System has produced positive results in single-center prospective registries of patients with FP and IF lesions, with reduced adjunctive PTA, minimal adjunctive stenting, and competitive 6-month and 12-month patency rates. In the observational non-randomized TALON (Treating Peripherals with SilverHawk: Outcomes Collection) registry, freedom from target lesion re-vascularization was 80 % for 87 patients at 12 months. Questions remaining for further research with this device include more accurate determination of an event rate for distal embolization, the appropriate use of distal protection, the value of and appropriate circumstances for adjunctive angioplasty, and definitive patency and clinical outcomes.
Indes et al (2010) evaluated the outcomes of atherectomy versus subintimal angioplasty (SIA) in patients with lower extremity arterial occlusive disease. From September 2005 through July 2006, 27 patients (17 women; mean age of 65 years, range of 37 to 85) underwent atherectomy of 46 lesions (11 TASC C/D occlusions) with the SilverHawk device. Results were compared to 67 patients (34 men; mean age of 69 years, range of 46 to 92) undergoing SIA for 67 lower extremity arterial occlusions from July 1999 through June 2004. Technical success in the atherectomy cohort was 100 %. In the 11 patients with occlusions, symptoms improved in 10 and worsened in 1, but 9 (82.0 %) of the 11 patients required re-intervention, and 8 (72.7 %) patients with occlusive lesions re-occluded. Endovascular re-intervention was required to maintain primary patency in only 2 (12.5 %) of 16 patients treated for stenotic lesions. At 1 year, the assisted primary patency was 37.7 % in the atherectomy group. In the 11 patients with occlusive lesions, the patency rates were 36.8 % and 12.3 % at 6 and 9 months, respectively, versus 100 % and 83.3 % at the same time intervals in patients with stenotic lesions. Subintimal angioplasty was technically successful in 56 (83.6 %) of 67 occlusions. The assisted primary patency and limb salvage rates of the entire group (intention-to-treat) at 12 and 24 months were 59.2 % and 45.0 %, respectively, while the assisted primary patency of the 56 technically successful SIAs at 12 and 24 months were 70.7 % and 53.8 %, respectively. Limb salvage for the entire group (intention-to-treat) was 90.6 % and 87.9 % at 12 and 24 months, respectively. The authors concluded that atherectomy may yield acceptable primary patency and limb salvage in patients with stenotic lesions. Many of the patients treated for occlusive lesions require re-intervention. Based on patency and limb salvage, SIA appears superior to atherectomy for the treatment of lower extremity occlusive disease.

Sixt and co-workers (2010) reported the acute and long-term outcome of Silverhawk- assisted atherectomy for femoropopliteal lesions. In this prospective study, de novo and re-stenotic lesions of the femoropopliteal segments were treated with the Silverhawk device. A total of 161 consecutive patients (164 lesions) with PAD Rutherford classes 2 to 5 were included
from June 2002 to October 2004 and October 2006 to June 2007 (59 % male, mean age of 67 +/- 11 years, range of 40 to 88) and the outcome analyzed according to the TASC II classification. Directional atherectomy alone was performed successfully in 28 % (n = 46), adjunctive balloon angioplasty in 65 % (n = 107) and stenting in 7 % (n = 11). The overall technical success rate was 76 % (124/164) and the procedural success rate 95 % (154/164). At 12 months primary patency rate was 61 % (85/140) and the secondary patency rate was 75 % (105/140) in the entire cohort, being less favorable in TASC D compared to TASC A to C lesions (p = 0.034 and p < 0.001, respectively). Furthermore, the re-stenosis rate differed trendwise (p = 0.06) between de novo and re-stenotic lesions. Changes in the ankle-brachial index (ABI) and the Rutherford classes were significantly in favor of TASC A to C lesions compared to TASC D after 12 months (p = 0.004). The event free survival (myocardial infarction, transient ischemic attack, or re-stenosis) was 48 % at 12 months and 38.5 % at 24 months. Predictor for re-stenosis in the multi-variable analysis was only male gender (p = 0.04). The authors concluded that the results in TASC D lesions are inferior to those in the lesser stages. Directional atherectomy of femoro-popliteal arteries showed a trend to better long-term technical and clinical outcome in de novo lesions compared to re-stenotic lesions.

Jaff et al (2010) analyzed therapeutic strategies, outcomes, and medical cost of treatment among Medicare patients with PAD. Patients who underwent therapy for PAD were identified from a 5 % random sample of Medicare beneficiaries from Medicare Standard Analytic Files for the period 1999 to 2005. Clinical outcomes (death, amputation, new clinical symptoms related to PAD) and direct medical costs were examined by chosen re-vascularization options (endovascular, surgical, and combinations). One-year PAD prevalence increased steadily from 8.2 % in 1999 to 9.5 % in 2005. The risk-adjusted time to first post-treatment clinical outcome was lowest in those treated with PTA or atherectomy and stents (hazard ratio [HR], 0.829; 95 % confidence interval [CI]: 0.793 to 0.865; p < 0.001) and stents only (HR, 0.904; 95 % CI: 0.848 to 0.963; p = 0.002) compared with PTA alone. The lowest per patient risk-adjusted costs during the quarter of the first observed treatment were associated with "PTA
and stents" ($15,197), and stents only ($15,867). Risk-adjusted costs for surgical procedures (bypass and endarterectomy) were $27,021 during the same period. Diabetes was present in 61.7% of the PAD population and was associated with higher risks of clinical events and higher medical costs compared with PAD patients without diabetes. The authors concluded that clinical and economic burden of PAD in the Medicare population is substantial, and the interventions used to treat PAD are associated with differences in clinical and economic outcomes. They stated that prospective cost-effectiveness analyses should be included in future PAD therapy trials to inform payers and providers of the relative value of available treatment options.

Guidance from the National Institute for Health and Clinical Excellence (NICE, 2011) concluded that "current evidence on the efficacy of percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices is inadequate in quality. Evidence on safety is inadequate, specifically with regard to the risk of distal embolisation. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research." The NICE guidance stated that further research into percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices should take the form of well-conducted trials, which should define patient selection, treatment protocols and location and types of arterial lesions treated, and report long-term patency outcomes.

An interventional procedure consultation document on percutaneous laser atherectomy for peripheral arterial disease from the National Institute for Health and Clinical Excellence (2011) concluded: "The evidence on percutaneous laser atherectomy for peripheral arterial disease raises no major safety concerns. Current evidence on its efficacy is inadequate in quantity and quality (in particular, the technical indications for the procedure are not well described in the published literature). Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research." The consultation document stated that further research should describe the criteria for selection of patients and
report clearly whether percutaneous laser atherectomy was used instead of conventional balloon angioplasty (and the reasons for this) or whether balloon angioplasty was attempted but found not to be feasible. In addition, reports should specify whether the procedure was used alone to recanalize arteries or with adjunctive balloon angioplasty and/or stenting. When percutaneous laser atherectomy is used instead of balloon angioplasty, then studies should compare the outcomes of the two procedures. Reported outcomes should include objective evidence of arterial patency and blood flow in addition to clinical effects. The consultation documents noted that long-term follow-up (2 years and beyond) would be useful.

Guidance from the National Institute for Health and Clinical Excellence (NICE, 2012) on percutaneous laser angioplasty concluded: "Current evidence on the efficacy and safety of percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit." The guidance stated that patient selection should be carried out by a vascular multidisciplinary team including a vascular surgeon and a vascular interventional radiologist. The guidance stated that the multidisciplinary team should consider carefully whether using percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease is likely to have any benefits over conventional recanalization by balloon angioplasty (with or without stenting) alone. The specialist advisers to NICE listed key efficacy outcomes as an increase in arterial diameter and blood flow, tissue healing, symptom relief, improvement in quality of life, amputation-free survival and reintervention rates. The NICE committee noted that much of the evidence on this procedure is not recent, and that a limited amount of the older evidence described using laser alone for atherectomy but more recent evidence focused on its use as an adjunct to balloon angioplasty (with or without stenting). This more recent evidence and the advice of specialists underpinned the decision to evaluate laser recanalization as an adjunctive procedure. The NICE guidance noted, while the committee
considered the evidence adequate to recommend normal arrangements for the use of percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting), it remained uncertain about whether its use confers any advantages over balloon angioplasty alone and, if so, in which patients.

The Trellis® Peripheral Infusion System has been developed as a percutaneous mechanical thrombectomy treatment for deep vein thrombosis (DVT) that does not respond adequately to anticoagulant and/or thrombolytic therapy. This system consists of a specially designed catheter that is connected to a handheld motorized control unit. Guided by ultrasonographic images, the Trellis catheter is inserted into an appropriate vein and advanced to the thrombosis. A guidewire is threaded through the clot; next the catheter is advanced into the clot so that the distal end of the catheter passes completely through the clot but the proximal end of the catheter does not enter the clot. At this point in the procedure, balloons in the proximal and distal ends of the catheter are inflated to seal off the section of the vein containing the clot, a thrombolytic agent is injected through the catheter into the clot, and the motor is activated, which causes rotation of a sinusoidally shaped wire that lies between the inflated balloons. The combined action of the thrombolytic agent and rotating wire disrupt the clot, and the disrupted material can be aspirated through the catheter. After clot removal, the balloons are deflated and the catheter is removed. The procedure using the Trellis system has been referred to as isolated segmental pharmacomechanical thrombolysis.

The Trellis Infusion System received FDA 515(k) clearance (K013635) on December 11, 2002. According to the clearance summary, the Trellis Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

The Trellis Plus Infusion System received 510(k) clearance (K021958) on July 3, 2002. The system is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.
The Trellis Reserve Infusion System received 510(k) clearance (K023514) on December 2, 2002. The Trellis™ Reserve Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

A “Modification to the Trellis Reserve Infusion System” received 510(k) clearance (K032261) on August 22, 2003. According to the clearance summary, the Trellis™ Reserve Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. The Trellis Reserve Infusion System is equivalent to the predicate product, the original Trellis Reserve Infusion System. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. Bacchus Vascular, Inc. believes the Trellis Reserve Infusion System is substantially equivalent to existing legally marketed devices.

The Trellis-8 Peripheral Infusion System received 510(k) clearance (K050147) on February 3, 2005. According to the clearance summary the Trellis™-8 Peripheral Infusion System is intended for controlled and selective infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature.

The Trellis-6 Peripheral Infusion System received 510(k) clearance (K071664) on July 13, 2007. According to the clearance summary the Trellis™-6 Peripheral Infusion System is intended for controlled and selective infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature. The system enables the physician to isolate a treatment region, infuse a physician-specified fluid, and disperse the fluid by means of oscillation of a Dispersion Wire. The Isolation/Infusion component is a multi-lumen catheter with two compliant balloons at the distal end and infusion holes located between these balloons. The device also has a central through-lumen that is compatible with a 0.035” guidewire. The Dispersion Wire provides oscillation when activated. The Dispersion Wire is connected to an integral Oscillation Drive Unit that oscillates the Dispersion Wire within the isolated region to further disperse the infused fluid. If desired by the physician, post procedure
aspiration of the isolated area between the occluding balloons may be accomplished through the catheter by using the guidewire lumen.

Papantoniou et al (2013) stated that Paget-Schroetter syndrome (PSS) is a rare form of thoracic outlet syndrome caused by axillo-subclavian vein thrombosis that typically presents in healthy young adults. Prompt therapy, traditionally by means of catheter-directed thrombolysis (CDT) prior to definitive surgery, can prevent the subsequent onset of post-thrombotic syndrome (PTS) and considerable disability. As CDT is associated with major hemorrhage and high overall treatment cost, pharmaco-mechanical thrombectomy (PMT) seems to be an attractive alternative that combines pharmacological thrombolysis with mechanical clot disruption. The Trellis-8 peripheral infusion catheter is an example of such a treatment, which provides topical thrombolysis in an isolated zone. These investigators described the use of the Trellis-8 PMT system in the successful management of 3 patients with PSS.

Furthermore, an UpToDate review on “Primary (spontaneous) upper extremity deep vein thrombosis” (Goshima, 2014) states that “Mechanical thrombolysis (e.g., Trellis, AngioJet, EKOS catheter) is often used in combination with pharmacologic thrombolysis. There are limited data involving the use of these devices to treat upper extremity thrombosis”. Moreover, mechanical thrombolysis is not mentioned in the “Summary and Recommendations” of this review.

In a Cochrane review, Wasiak and colleagues (2012) examined the effects of percutaneous transluminal coronary rotational atherectomy (PTCRA) for coronary artery disease in patients with non-complex and complex lesions (e.g., ostial, long or diffuse lesions or those arising from in-stent re-stenosis) of the coronary arteries. For the original review, these investigators searched the Heart Group Specialised Register; The Cochrane Library to Issue 2, 2001; and MEDLINE, CINAHL, EMBASE and Current Contents to December 2002 and reviewed reference lists for relevant articles. For the current review, they searched the same registries from 2002 to 2012 and reviewed reference lists for relevant articles.
These researchers included randomized and quasi-randomized controlled trials of PTCRA compared with placebo, no treatment or another intervention and excluded cross-over trials. Two review authors independently extracted data and assessed the risk of bias of the studies identified. Data were extracted independently by 2 review authors. They asked authors of trials to provide information when missing data were encountered. Statistical summaries used risk ratios (RR) and weighted mean differences. These researchers included 12 trials enrolling 3,474 patients. The overall risk of bias was unclear for the majority of articles due to a lack of reported data; however, the authors determined that this would be unlikely to impact negatively as most data outcomes were objective (e.g., death versus no death). There was no evidence of the effectiveness in improving patient outcomes of PTCRA in non-complex lesions. In complex lesions, there were no statistically significant differences in restenosis rates at 6 months (RR 1.05; 95% confidence interval (CI): 0.83 to 1.33) and at 1 year (RR 1.21; 95% CI: 0.95 to 1.55) in those receiving PTCRA with adjunctive balloon angioplasty (PTCA) (PTCRA/PTCA) compared to those receiving PTCA alone. Morphological characteristics distinguishing complex lesions have not been examined in parallel-arm randomized controlled trials. The evidence for the effectiveness of PTCRA in in-stent re-stenosis was unclear. Compared to angioplasty alone, PTCRA/PTCA did not result in a statistically significant increase in the risk of major adverse cardiac events (myocardial infarction (MI), emergency cardiac surgery or death) during the in-hospital period (RR 1.27; 95% CI: 0.86 to 1.90). Compared to angioplasty, PTCRA was associated with 9 times the risk of an angiographically detectable vascular spasm (RR 9.23; 95% CI: 4.61 to 18.47), 4 times the risk of perforation (RR 4.28; 95% CI: 0.92 to 19.83) and about twice the risk of transient vessel occlusions (RR 2.49; 95% CI: 1.25 to 4.99) while angiographic dissections (RR 0.48; 95% CI: 0.34 to 0.68) and stents used as a bailout procedure (RR 0.29; 95% CI: 0.09 to 0.87) were less common. The authors concluded that when conventional PTCA is feasible, PTCRA appears to confer no additional benefits. There is limited published evidence and no long-term data to support the routine use of PTCRA in in-stent re-stenosis. Compared to angioplasty alone, PTCRA/PTCA did not result in a higher incidence of major adverse cardiac events, but
patients were more likely to experience vascular spasm, perforation and transient vessel occlusion. In certain circumstances (e.g. patients ineligible for cardiac surgery, those with architecturally complex lesions, or those with lesions that fail PTCA), PTCRA may achieve satisfactory re-vascularization in subsequent procedures.

An UpToDate review on “Specialized revascularization devices in the management of coronary heart disease” (Cutlip, 2014) states that “Rotational atherectomy summary -- The American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) guideline update for PCI concluded that there is no evidence that rotational atherectomy improves late outcomes in lesions that can be safely treated with stenting or angioplasty alone. When rotational atherectomy is being considered, the weight of evidence or opinion was in favor of the efficacy of IVUS for establishing the presence and distribution and coronary calcium. However, in our practices, IVUS is rarely used for this indication”.

Beschorner and Zeller (2014) stated that mechanical atherectomy for in-stent restenosis (ISR) appeared to be limited by a low patency rate. This might be due to the mechanical trauma that induces an inflammatory response leading to recurrent ISR. Addition of drug-eluting balloon (DEB) angioplasty could overcome these challenges while preserving the advantages of a better acute result. However, the authors concluded that due to lack of clinical data, combination of atherectomy and DEB remains an experimental procedure for ISR treatment.

**Drug-Eluting Balloons for the Treatment of Primary Lesion/Occlusion of Peripheral Arteries:**

The Australian Safety and Efficacy Registry of New Interventional Procedures’ Technology Brief on “Drug-eluting stents and balloons for the treatment of peripheral vascular disease” (2012) considered DEBs to be investigational.

In a meta-analysis, Yang and colleagues (2014) evaluated the clinical value of primary stenting for treating PADs in below-
the-knee arteries by comparing to PTA. PubMed, ScienceDirect, Embase, and CBM databases were searched for relevant articles. Based on the different types of stents, these researchers divided the primary stent group into the bare metal stent (BMS) group and drug-eluting stent (DES) group. The outcome measures were immediate technical success, freedom from target vessel revascularization (TVR-free) rate and limb salvage. A total of 14 studies (published between 2001 and 2012) satisfying the inclusion criteria were identified; 3,278 patients and 3,699 limbs constituted the final study population. The technical success rate of PTA was 90.95 \% (95 \% CI: 86.25 \% to 94.15 \%). Only 1 study reported a technical failure of 4 \% (5/118) in the primary stent group. There were no significant differences in the 1-year primary patency and TVR-free rates between the PTA group and BMS groups (p > 0.05 and p > 0.05), respectively. The pooled estimates of 1-year primary patency and TVR-free rate in DES group were 85.05 \% (95 \% CI: 79.95 \% to 89.02 \%) and 90.52 \% (95 \% CI: 83.68 \% to 94.67 \%), respectively, which were better than those of the BMS (p < 0.001) and PTA groups (p < 0.001).

The pooled estimate of 1-year limb salvage in the PTA, BMS, and DES groups was 88.41 \% (95 \% CI: 84.53 \% to 91.43 \%), 94.41 \% (95 \% CI: 89.52 \% to 97.1 \%), and 96.81 \% (95 \% CI: 94.04 \% to 98.32 \%), respectively. The BMS and DES groups had higher limb salvage rates than the PTA group (p < 0.001 for both comparisons). The rates of severe complications were low both in the PTA and primary stent groups. Although the influence analysis showed rather robust results, the heterogeneity was quite high and they were not adjusted for confounding variables. The authors concluded that primary BMS implantation had no advantage over PTA in reducing restenosis or re-vascularization for infra-popliteal disease; primary DES implantation appeared to be a promising treatment for focal infra-popliteal lesions. (The MeSH terms of this article included balloon).

In a Cochrane review, Chowdhury et al (2014) determined the effect of percutaneous transluminal angioplasty (PTA) compared with PTA with bare metal stenting (BMS) for superficial femoral artery (SFA) stenoses on vessel patency in people with symptomatic (Rutherford categories 1 to 6; Fontaine stages II to IV) lower limb peripheral vascular disease. In addition, these
Researchers assessed the efficacy of PTA and stenting in improving quality of life, ankle brachial index (ABI) and treadmill walking distance. For this update the Cochrane Peripheral Vascular Diseases Group Trials Search Coordinator searched the Specialised Register (last searched August 2013) and the Cochrane Central Register of Controlled Trials (CENTRAL) (Issue 6, 2013). Randomized trials of angioplasty alone versus angioplasty with BMS for the treatment of superficial femoral artery stenosis were selected for analysis. Two review authors independently selected suitable trials, assessed trial quality and extracted data. Furthermore, these 2 review authors performed assessments of methodological quality and wrote the final manuscript. The third review author (ADM) cross-checked all stages of the review process. These investigators included 3 new studies in this update, making a total of 11 included trials with 1,387 participants. The average age was 69 years and all trials included men and women. Participants were followed for up to 2 years.

There was an improvement in primary duplex patency at 6 and 12 months in participants treated with PTA plus stent over lesions treated with PTA alone (6 months: odds ratio (OR) 2.90, 95% confidence interval (CI): 1.17 to 7.18, p = 0.02, 6 studies, 578 participants; 12 months: OR 1.78, 95% CI: 1.02 to 3.10, p = 0.04, 9 studies, 858 participants). This was lost by 24 months (p = 0.06). There was a significant angiographic patency benefit at 6 months (OR 2.49, 95% CI: 1.49 to 4.17, p = 0.0005, 4 studies, 329 participants) which was lost by 12 months (OR 1.30, 95% CI: 0.84 to 2.00, p = 0.24, 5 studies, 384 participants); ABI and treadmill walking distance showed no improvement at 12 months (p = 0.49 and p = 0.57, respectively) between participants treated with PTA alone or PTA with stent insertion. Three trials (660 participants) reported quality of life, which showed no significant difference between participants treated with PTA alone or PTA with stent insertion at any time interval. Anti-platelet therapy protocols and inclusion criteria regarding affected arteries between trials showed marked heterogeneity. The authors concluded that although there was a short-term gain in primary patency there was no sustained benefit from primary stenting (PS) of lesions of the superficial femoral artery in addition to angioplasty. Moreover, they stated that future trials should focus on quality of life for claudication and limb salvage for critical ischemia.
Antoniou et al (2014) examined if treatment of infra-inguinal arterial occlusive disease with drug-eluting stents (DESs) provided improved outcomes compared with BMSs or PTA alone. Altogether, 136 papers were found using the reported searches, of which 5 provided the best evidence to answer the question. All papers represent either level 1 or 2 evidence. The authors, journal, date, country of publication, patient group studied, study type, relevant outcomes and results of these papers are tabulated. Main outcome measures varied among the studies, and included patency, in-stent restenosis, target lesion revascularization, major adverse events, clinical improvement and limb salvage. Evidence on the comparative efficacy of DESs in femoro-popliteal arterial disease is mainly based on 2 randomized, controlled trials (RCTs). Paclitaxel-eluting stents were evaluated in the Zilver PTX trial and demonstrated superior 2-year results to either BMSs or PTA, as indicated/shown by patency (DES versus PTA, 74.8 versus 26.5 %, p < 0.01), clinical benefit (DES versus PTA, P < 0.01) and event-free survival (DES vs PTA, 86.6 vs 77.9%, P = 0.02). However, the SIROCCO trial found that the sirolimus-eluting stent did not exhibit statistically significant differences in 2-year in-stent re-stenosis (22.9 versus 21.1 %) and target lesion re-vascularization (6 versus 13 %) compared with the BMS. Treatment of infra-politeal arterial disease with DESs was related with superior outcomes to those of BMSs, as indicated/shown by patency, freedom from target lesion revascularization and freedom from major adverse events. Furthermore, the ACHILLES trial, the only published trial comparing the infra-popliteal DES with PTA, revealed lower angiographic restenosis (22.4 versus 41.9 %, p = 0.019) and greater vessel patency (75 versus 57.1 %, p = 0.025) in the DES group at 1 year. However, data related to clinical parameters in patients with critical limb ischemia secondary to infra-geniculate arterial disease, such as limb salvage and ulcer healing, are insufficient. The authors concluded that treatment of infra-inguinal arterial disease with DES was safe and appeared to be superior to treatment with PTA alone or BMS. They stated that the role of DES in sustained improvement in clinical outcome end-points, such as limb salvage, remains to be elucidated.

There is Cochrane “protocol” to evaluate the effectiveness of

Limpijankit (2015) stated that “Over the past decade, drug-coated balloons (DCBs) have emerged as an exciting new therapeutic option to prevent restenosis in the treatment of peripheral vascular disease .... In this year, 3 major pivotal trials have confirmed the safety and efficacy of paclitaxel-coated balloons in the endovascular treatment of femoropopliteal artery disease. These are the Drug-Coated Balloon Versus Standard Percutaneous Transluminal Angioplasty for the Treatment of Superficial Femoral and/or Popliteal Peripheral Artery Disease (IN.PACT SFA) trial, the Lutonix Paclitaxel-Coated Balloon for the Prevention of Femoropopliteal Restenosis 2 (LEVANT 2) trial, and 5-year follow-up of the Local Taxan With Short Time Contact for Reduction of Restenosis in Distal Arteries (THUNDER) trial .... Although the initial findings are encouraging, long-term follow-up will be useful in determining whether the benefit of these new devices is sustained, increased, or attenuated over time. In the LEVANT 2 trial, the primary patency endpoint from the Kaplan-Meier curves seem to drop distinctly in the Lutonix arm after 12 months, while the control arm remained unchanged .... although DCBs are generally safe and superior to standard balloon angioplasty, there are many unanswered questions about DCB technology. The results of these trials cannot be generalized to patients not included in these trials. Future studies should be performed in longer lesions, densely calcified lesions, or in-stent restenosis, and consider comparison with bare metal stents and drug-eluting stents. Trials combining DCBs with atherectomy (Atherectomy Followed by a Drug Coated Balloon to Treat Peripheral Arterial Disease [DEFINITIVE AR] trial) are being conducted to clarify if there is an additive effect. Another inconclusive issue is the appropriateness use of these devices. Which patient should be a good candidate for using these DCBs
as the first-line therapy instead of standard balloon? In order to justify their broad use, the DCBs must show reduction in repeat revascularization, cost benefit, and improving quality of life. Another concern is the learning curve of how to use the DCBs to ensure proper uptake of the drug and minimize downstream drug loss. This is important to maximize the results of treatment. Post-approval study is also suitable for longer-term follow-up, which is certainly needed to confirm the durability of the benefit”.

In a Cochrane review, Bekken et al (2015) examined the effects of PTA versus PS for stenotic and occlusive lesions of the iliac artery. The Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator searched the Specialised Register (last searched April 2015) and Cochrane Register of Studies (CRS) (Issue 3, 2015). The TSC searched trial databases for details of ongoing and unpublished studies. These researchers included all RCTs comparing PTA and primary stenting for iliac artery occlusive disease. They excluded quasi-randomized trials, case reports, case-control or cohort studies. They excluded no studies based on the language of publication. Two authors independently selected suitable trials. JB and HJ independently performed data extraction and trial quality assessment. When there was disagreement, consensus would be reached first by discussion among both authors and, if still no consensus could be reached, through consultation with BF. These investigators identified 2 RCTs with a combined total of 397 participants as meeting the selection criteria. One study included mostly stenotic lesions (95 %), whereas the second study included only iliac artery occlusions. Both studies were of moderate methodological quality with some risk of bias relating to selective reporting and non-blinding of participants and personnel. The overall quality of evidence was low due to the small number of included studies, the differences in study populations and definitions of the outcome variables. Due to the heterogeneity among these 2 studies it was not possible to pool the data. Percutaneous transluminal angioplasty with selective stenting and primary stenting (PS) resulted in similar improvement in the stage of peripheral arterial occlusive disease according to Rutherford's criteria, resolution of symptoms and signs, improvement of
quality of life, technical success of the procedure and patency of the treated vessel. Improvement in walking distance as reported by the patient, measured claudication distance, ulcer healing, major amputation-free survival and delayed complications (greater than 72 hours) were not reported in either of the studies. In 1 trial, PTA of iliac artery occlusions resulted in a significantly higher rate of major complications, especially distal embolization. The other trial showed a significantly higher mean ABI at 2 years in the PTA group (1.0) compared to the mean ABI in the PS group (0.91); mean difference (MD) 0.09 (95 % CI: 0.04 to 0.14; p value = 0.001, analysis performed by review authors). However, at other time-points there was no difference. These researchers considered it unlikely that this difference was attributable to the study procedure, and also believed this difference may not be clinically relevant. The authors concluded that there is insufficient evidence to assess the effects of PTA versus PS for stenotic and occlusive lesions of the iliac artery. From 1 study it appeared that PS in iliac artery occlusions may result in lower distal embolization rates. They stated that more studies are needed to come to a firm conclusion.

Furthermore, an UpToDate review on “Percutaneous interventional procedures in the patient with lower extremity claudication” (Zaetta et al, 2016) states that “Drug-eluting balloons -- A number of medical therapies aimed at preventing restenosis after femoral PTA have been tried, but only local delivery of paclitaxel has been shown to improve outcomes. Local delivery of paclitaxel was initially studied in the coronary circulation, but subsequently drug-eluting balloons (e.g., Lutonix, IN.PACT Admiral) have been approved for use in the United States as a means to deliver paclitaxel and have been used in the femoropopliteal segment. Whether the reduced number of interventions that results offsets the additional expense of the drug-coated balloon remains to be determined”.

Herten et al (2016) stated that PAD, particularly critical limb ischemia, is an area with urgent need for optimized therapies because; to-date, vascular interventions often have limited life spans. In spite of initial encouraging technical success after femoro-popliteal percutaneous transluminal angioplasty or
Stenting, post-procedural re-stenosis remains the major problem. The challenging idea behind the DCB concept is the biological modification of the injury response after balloon dilatation. Anti-proliferative drugs administered via DCBs or drug-eluting stents are able to suppress neointimal hyperplasia, the main cause of re-stenosis. These investigators reviewed the results of DCB treatments of femoro-popliteal and infra-popliteal lesions in comparison to standard angioplasty with uncoated balloons. A systematic literature search was performed in (i) medical journals (i.e., Medline), (ii) international registers for clinical studies (i.e., www.clinicaltrials.gov), and (iii) abstracts of scientific sessions.

Several RCTs with follow-up periods of up to 5 years demonstrated the effectiveness of paclitaxel-DCB technology. However, calcified lesions appeared to affect the effectiveness of DCB. Combinations of pre-conditioning methods with DCBs showed promising results. Although the mechanical abrasion of calcium via atherectomy or laser ablation showed favorable peri-procedural results, the long-term impact on re-stenosis and clinical outcome has to be demonstrated. Major advantages of the DCBs are the rapid delivery of drug at uniform concentrations with a single dose, their effectiveness in areas wherein stents have been contraindicated until now (i.e., bifurcation, ostial lesions), and in leaving no stent scaffold behind. Re-interventions are easier to perform because DCBs leave no metal behind. The authors concluded that various combinations of DCBs with other treatment modalities may prove to be viable options in future; there is still a lack of respectable prospective long-term data to state the long-term superiority of one DCB technology.

Steiner et al (2016) examined patient outcomes following the use of the Lutonix DCB in patients undergoing endovascular intervention in below-the-knee (BTK) arteries. A retrospective chart review identified 248 patients who were treated for symptomatic PAD with the Lutonix DCB between May 2013 and October 2014. A total of 40 patients were lost to follow-up, leaving 208 patients (mean age of 74.1±9.7 years; 138 men) with evaluable data for outcome analysis. The patient cohort suffered from either severe claudication (38.6 %) or critical limb ischemia (CLI; 61.4 %) in 220 limbs. Almost 2/3 (140, 63.6 %) of the 220 target lesions were total occlusions, and 37 (17.8 %) of all
patients had occlusion of all 3 BTK vessels before intervention. Over a median 9-month follow-up, TLR occurred in 15.9 % of patients with an average time to first re-intervention of 8 months. In total, 39 amputations were performed in 31 limbs. However, 17 of these amputations were pre-planned minor amputations below the ankle; only 9 (4.1 %) major amputations occurred corresponding to 6.6 % of the CLI cohort. Freedom from the composite of death or major amputation was estimated as 92 % and 85 % at 6 and 12 months, respectively, by Kaplan-Meier analysis. In the full cohort, improvement of at least 1 Rutherford category was seen in 130 (59.1 %) limbs after 1 year or at the last follow-up, with 104 (80.0 %) of those limbs showing an improvement of greater than or equal to2 categories. The authors concluded that from this single-center experience, the Lutonix DCB showed therapeutic promise in a disease state where new treatment options are needed.

In a prospective, single-center, non-randomized study, Werner et al (2016) evaluated the safety and effectiveness of the Igaki-Tamai biodegradable scaffold after DEB angioplasty in patients with occlusive SFA disease. A total of 20 patients (mean age 66.7 ± 11.6 years; 14 men) with symptomatic de-novo SFA lesions undergoing angioplasty with the In.Pact Admiral paclitaxel-coated balloon and subsequent implantation of the Igaki-Tamai bioresorbable scaffold were included in this study. All patients were claudicants. The average diameter stenosis was 89.7 %, and the mean length was 43.6 mm. Clinical examinations with duplex sonography were performed after 1, 6, 9, and 12 months. The main study outcomes were technical success, re-stenosis, TLR, ABI improvement, and changes in quality of life (QOL) evaluated with the walking impairment questionnaire. Safety was assessed by monitoring the occurrence of AEs. Angioplasty with a paclitaxel-coated balloon was performed in all patients, resulting in an average diameter stenosis of 24 %. Subsequent implantation of the Igaki-Tamai scaffold reduced the average diameter stenosis to 3.5 %. In the first 6 months, 2 cases of re-stenosis were reported, with no TLRs within that period. However, by the 12-month follow-up in 19 patients, 11 patients had lost in-stent patency. Among these patients, 8 had TLRs, which were the only AEs recorded that were referable to the
procedure; QOL assessments showed improvement in the majority of patients. The authors concluded that the findings of the GAIA-DEB study showed that DEB treatment of the femoral artery prior to the implantation of the biodegradable Igaki-Tamai scaffold was safe; however, the anti-proliferative actions of paclitaxel in the vessel wall were not effective in preventing restenosis, which occurred predominantly after 6 months.

Grotti et al (2016) reported the 3-year safety and effectiveness outcomes from the prospective all-comers DEBATE-ISR study of symptomatic diabetic patients with femoro-popliteal ISR undergoing treatment with paclitaxel-eluting balloons compared with historical diabetic controls. From January 2010 to December 2011, a total of 44 consecutive diabetic patients (mean age of 74 ± 11 years; 32 men) were treated with DEBs and enrolled in the study. The control group comprised 42 consecutive diabetic patients (mean age 76 ± 7 years; 23 men) treated with conventional balloon angioplasty (BA) from 2008 to 2009. No significant differences in terms of clinical, angiographic, or procedural characteristics were observed between the study groups; CLI was present in the majority of patients. Tosaka class III ISR was observed in more than 50% of the patients. Mean lesion length was 132 ± 86 and 137 ± 82 mm in the DEB and BA groups, respectively (p = 0.7). At 3-year follow-up, the rate of TLR was 40% in the DEB group versus 43% in the BA group (p = 0.8); Kaplan-Meier analysis showed no significant differences in terms of freedom from TLR. The presence of a Tosaka class III occlusion was associated with a worse outcome in both study groups (OR 3.96, 95% CI: 1.55 to 10.1, p = 0.004). The authors concluded that using DEBs for femoro-popliteal ISR yielded similar results to BA in terms of TLR at 3-year follow-up. The treatment of more complex ISR lesions was associated with an increased rate of TLR, irrespective of the technology used.

In a Cochrane review, Kayssi et al (2016) evaluated the effectiveness of DEBs compared with uncoated, non-stenting balloon angioplasty in people with symptomatic lower-limb PAD. The authors concluded that based on a meta-analysis of 11 trials with 1,838 participants, there is evidence of an advantage for DEBs compared with uncoated balloon angioplasty in several
anatomic end-points (e.g., primary vessel patency [high-quality evidence], binary restenosis rate [moderate-quality evidence], and target lesion revascularization [low-quality evidence] for up to 12 months). On the other hand, there is no evidence of an advantage for DEBs in clinical end-points (e.g., amputation, death, or change in ABI, or change in Rutherford category during 12 months’ follow-up). They stated that well-designed randomized trials with long-term follow-up are needed to compare DEBs with uncoated balloon angioplasties adequately for both anatomic and clinical study end-points before the widespread use of this expensive technology can be justified.

Drug-Eluting Balloon for Vein Grafts and Dialysis/Vascular Accesses:

Bjorkman and colleagues (2016) analyzed outcomes of the first experiences with DEBs in native arteries, vein grafts, and vascular accesses. The study was also a pilot for the authors’ future prospective, randomized, and controlled studies regarding the use of DEBs in the treatment of the stenosis in bypass vein graft and dialysis access. A total of 93 consecutive patients were retrospectively analyzed and 81 were included in the study. Inclusion criteria included at least 1 previous percutaneous angioplasty to the same lesion. Patients were divided into 3 groups according to the anatomical site of the lesion: (i) native lower limb artery, (ii) vein bypass graft, or (iii) vascular access. Time from the previous percutaneous angioplasty to the DEB was compared to the time from the DEB to end-point in the same patient. End-points included any new re-vascularization of the target lesion, major amputation, or new vascular access. The median time from the DEB to end-point was significantly longer than the median time from the preceding percutaneous angioplasty to DEB in all 3 groups. This difference was clearest in native arteries and vein grafts, whereas the difference was smaller from the beginning and disappeared over time in the vascular access group. No significant differences were seen between the groups with regard to smoking, antiplatelet regime, diabetes, Rutherford classification, or sex. The authors concluded that although the setup of this study had several limitations, the results suggested that there could be benefit from DEBs in
Moreover, they stated that very little data have been published on the use of DEBs in vein grafts and vascular accesses, and randomized and controlled prospective studies are needed to further investigate this field.

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**HCPCS codes not covered for indications listed in the CPB:**

- C2623 Catheter, transluminal angioplasty, drug-coated, non-laser [drug-eluting balloon in combination with mechanical or laser peripheral atherectomy]

**ICD-10 codes covered if selection criteria are met:**
Isolated segmental pharmacomechanical thrombolysis (Trellis Peripheral Infusion System):

No specific code

ICD-10 codes not covered for indications listed in the CPB (not all inclusive):

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<td>[Paget-Schroetter syndrome]</td>
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The above policy is based on the following references:

7. White CJ. Peripheral atherectomy with the Pullback
19. Parrella A, Mundy L. SilverHawk Peripheral Plaque Excision System: Percutaneous peripheral atherectomy for patients
with peripheral vascular disease. Horizon Scanning Prioritising Summary - Volume 10. Adelaide, SA: Adelaide Health Technology Assessment (AHTA) on behalf of National Horizon Scanning Unit (HealthPACT and MSAC); 2005.


45. Cutlip D. Specialized revascularization devices in the management of coronary heart disease. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed December 2014.


Trellis Peripheral Infusion System


**Drug-Eluting Balloons for the Treatment of Primary Lesion/Occlusion of Peripheral Arteries**


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number:
CPB 0295 - Peripheral Atherectomy

There are no amendments for Medicaid.