AETNA BETTER HEALTH®

Clinical Policy Bulletin:
Peripheral Atherectomy and Thrombectomy Devices

Number: 0295

Policy

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.

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 mechanical or laser peripheral atherectomy in combination with drug-eluting balloon 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.

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%). Femoropopliteal (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 femoro-popliteal lesions. In this prospective study, de novo and re-stenotic lesions of the femoro-popliteal 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 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 re-stenosis 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 revascularization 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.

CPT Codes / HCPCS Codes / ICD-9 Codes

Other CPT codes related to the CPB:

32096   Thoracotomy, with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral

35511   Bypass graft, with vein; subclavian-subclavian

35512   subclavian-brachial

35516   subclavian-axillary

35518   axillary- axillary

35521   axillary-femoral

35525   brachial- brachial

35533   axillary-femoral- femoral

35537   aortoiliac

35538   aortobi-iliac

35539   aortofemoral

35540   aortobifemoral

35556   femoral-popliteal
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- 35558 femoral-femoral
- 35563 ilioiliac
- 35565 iliofemoral
- 35566 femoral-anterior tibial, posterior tibial, peroneal artery or other distal vessels
- 35570 tibial-tibial, peroneal-tibial, or tibial/peroneal trunk-tibial
- 35571 popliteal-tibial, -peroneal artery or other distal vessels
- 35583 In-situ vein bypass; femoral-popliteal
- 35585 femoral-anterior tibial, posterior tibial, or peroneal artery
- 35587 popliteal-tibial, peroneal
- 35637 Bypass graft, with other than vein; aortoiliac
- 35638 aortobi-iliac
- 37211 - 37214 Transcatheter therapy, arterial or venous infusion for thrombolysis
- 37220 - 37223 Revascularization, endovascular, open or percutaneous; iliac artery
- 37224 - 37227 femoral, popliteal artery(s)
- 37228 - 37235 tibial, peroneal artery
- 0234T Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; renal artery
- 0235T visceral artery (except renal), each vessel
- 0236T abdominal aorta
- 0237T brachiocephalic trunk and branches, each vessel
- 0238T iliac artery, each vessel

**ICD-9 codes covered if selection criteria are met:**

- 440.20 - 442.29 Atherosclerosis, of native arteries of the extremities
- 440.30 - 440.32 Atherosclerosis, of bypass graft of the extremities
**Isolated segmental pharmacomechanical thrombolysis (Trellis Peripheral Infusion System):**

No specific code

**ICD-9 codes not covered for indications listed in the CPB (not all inclusive):**

- 353.0 Brachial plexus lesions [Paget-Schroetter syndrome]
- 453.40 - 453.42 Venous embolism and thrombosis of deep vessels of lower extremity

The above policy is based on the following references:


Trellis Peripheral Infusion System


