Regence

Medical Policy Manual Surgery, Policy No. 109

Percutaneous Angioplasty and Stenting of Veins

Effective: March 1, 2026

Next Review: November 2026
Last Review: January 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Dilation and/or stent placement in veins is intended to restore blood flow in a narrowed or collapsed vein.

MEDICAL POLICY CRITERIA

Note: This policy addresses percutaneous angioplasty and stenting of **veins** only. This policy does *not* address percutaneous angioplasty and stenting of peripheral arteries, including repair of aneurysms, which may be considered medically necessary. Extracranial carotid angioplasty is addressed in a separate policy (see Cross References section).

I. Percutaneous transluminal angioplasty, with or without stenting, may be considered **medically necessary** for the treatment of venous stenoses for <u>any</u> of the following:

   A. Stenotic lesions of arteriovenous dialysis fistulas and grafts, and ipsilateral venous stenosis in the outflow of a functioning dialysis fistula and graft

   B. Superior or inferior vena cava syndrome with significant symptoms, from either extrinsic compression or intrinsic stenosis/occlusion [when standard treatments (i.e., radiation and/or chemotherapy) have failed]

C. Left iliac vein compression syndrome (May-Thurner Syndrome)

D. As an adjunct to prior or concurrent ipsilateral first rib resection for venous thoracic outlet syndrome due to persistent extrinsic compression (Paget-Schroetter syndrome) documented by pre-procedure imaging (i.e., ultrasound, venography, CT, or MRI)

E. Pulmonary vein stenosis

F. Thrombotic obstruction of major hepatic veins (Budd-Chiari syndrome)

G. Post-operative venous narrowing due to repair of sinus venosus atrial septal defect

H. Left renal vein compression (nutcracker syndrome) with significant signs or symptoms

I. Venous obstruction of an atrial baffle following Mustard or Senning repair of transposition of the great arteries

J. Symptomatic venous occlusion due to electrical device lead or central line placement

K. Portal vein stenosis in a liver transplant recipient

II. The use of angioplasty and/or endoprostheses for creation of intrahepatic shunt connections between the portal venous system and hepatic vein may be considered **medically necessary**.

III. Percutaneous transluminal angioplasty, with or without stenting, is considered **investigational** when policy criteria are not met and for all other venous indications, including but not limited to:

A. Deep vein thrombosis, venous stenosis, or venous insufficiency that is not related to the medically necessary indications above (I.A.- K.)

B. Chronic cerebrospinal venous insufficiency in multiple sclerosis or other conditions

C. Venous sinus obstruction or occlusion in idiopathic intracranial hypertension

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of symptoms, associated diagnoses and treatments

CROSS REFERENCES

1. Extracranial Carotid Angioplasty/Stenting, Surgery, Policy No. 93

BACKGROUND

PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF THE VEINS

Percutaneous transluminal angioplasty (PTA) of the veins is a procedure that has been used as an alternative to open vascular surgery in order to restore blood flow through narrowed veins. Techniques may include balloon angioplasty, laser angioplasty, and stent placement.

INTRAVASCULAR STENTS

Intravascular stents are used as an adjunct to angioplasty to prevent vessel wall collapse. They can be placed via transluminal catheters or placed with catheters during open vascular procedures. Drug-eluting stents are intended to prevent restenosis by reducing the growth of neointimal tissue. A number of different drugs are being evaluated for this use, including paclitaxel and sirolimus. These stents are coated with a mixture of synthetic polymers blended with the drug. A second coat of drug-free polymers is then added to serve as a diffusion barrier, thus allowing the gradual release of drug to the precise site of interest while avoiding systemic side effects.

ILIAC VEIN COMPRESSION SYNDROME

Iliac vein compression syndrome (IVCS) is deep vein thrombosis (DVT) that occurs as a result of compression of the left common iliac vein between the overlying right common iliac artery and the body of the fifth lumbar vertebra. This syndrome is relatively uncommon. If DVT occurs, it is treated with anticoagulation therapy. However, the underlying mechanical compression must be treated with surgery or stent placement. Left untreated it may result in recurrent DVT or postthrombotic syndrome (PTS) characterized by chronic swelling and pain in the affected extremity. Some patients also develop varicosities and stasis ulcers. This condition may also be referred to by other terms including but not limited to May-Thurner syndrome, non-thrombotic iliac vein lesions (NIVL), and Cockett syndrome.

PROXIMAL UPPER EXTREMITY VENOUS THROMBOSIS

Proximal upper extremity venous thrombosis occurs as a result of mechanical compression of the subclavian vein at the thoracic outlet. The natural history of the disorder is typically one of chronic venous obstruction with development of a painful, swollen extremity.[1, 2] Thrombosis may affect the brachiocephalic, subclavian, and/or axillary veins. Typical management of this condition involves thrombolysis and surgical decompression after a variable interval of oral anticoagulation. Venous stent placement may be helpful in maintaining patency of the vein following thoracic outlet decompression surgery that includes first rib resection. This condition may also be referred to by other terms including but not limited to axillary-subclavian venous thrombosis, effort thrombosis, Paget-Schroetter syndrome, or venous thoracic outlet syndrome.

IDIOPATHIC INTRACRANIAL HYPERTENSION

Idiopathic intracranial hypertension (IIH) is characterized by elevated intracranial pressure (ICP). The most common symptoms are headache and papilledema. Other symptoms include transient visual obscurations, pulsatile tinnitus, diplopia, and sustained visual loss. Initial evaluation of patients presenting with headache and papilledema consists of CT or MRI scan for possible hydrocephalus or tumor. Occlusion of the venous sinus, particularly the transverse sinus, is considered an uncommon cause of increased ICP. There has been some debate as to whether this occlusion is the cause or the effect of ICP. The hypothesis is that obstruction of venous return decreases venous outflow from the brain which also decreases

cerebrospinal fluid (CSF) outflow with subsequent increase in intracranial CSF pressure. Medical treatment includes medications that lower CSF production and/or therapeutic lumbar puncture. Since most patients with IIH are obese, weight loss is commonly recommended. If medical treatment fails to control IIH, surgical treatments include ventriculoperitoneal shunting, optic nerve sheath fenestration (optic nerve decompression), and subtemporal decompression. Angioplasty with stenting has been proposed for maintaining venous sinus patency. IIH may also be referred to as pseudotumor cerebri or benign intracranial hypertension, though these terms are considered inadequate and IIH is the preferred term.

CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY IN MULTIPLE SCLEROSIS

Multiple sclerosis (MS) is generally considered a chronic inflammatory demyelinating disease of the central nervous system (brain, spinal cord, and optic nerve) believed to be triggered by an autoimmune response to myelin. However, in part due to the periventricular predilection of the lesions of MS, vascular etiologies have also been considered. The core foundation of this vascular theory is that venous drainage from the brain is abnormal due to outflow obstruction in the draining jugular vein and/or azygos veins. This abnormal venous drainage, which is characterized by special ultrasound criteria, is said to cause intracerebral flow disturbance or outflow problems that lead to periventricular deposits. In the chronic cerebrospinal venous insufficiency (CCSVI) theory, these deposits have a similarity to the iron deposits seen around the veins in the legs of patients with chronic deep vein thrombosis. Balloon dilatation, with or without stenting, has been proposed as a means to treat the outflow problems, thereby alleviating CCSVI and MS complaints.

REGULATORY STATUS

While there are several types of stents that are approved by the U.S. Food and Drug Administration (FDA) for improvement of outflow for arteriovenous (A-V) access grafts in hemodialysis patients, and for the creation of intrahepatic shunt connections between the portal venous system and hepatic vein [i.e., transjugular intrahepatic portosystemic shunt (TIPS)], there are currently no stents with FDA approval for use in veins for any other indications.

In March 2017, the FDA issued a safety communication regarding the use of balloon angioplasty devices to treat autonomic dysfunction. This supplemented an earlier warning from the FDA concerning the potential for adverse events following endovascular interventions to treat CCSVI. Reports of adverse events obtained by the FDA included death, stroke, detachment and/or migration of stents, vein damage, thrombosis, cranial nerve damage, and abdominal bleeding. This communication included the caveat that clinical trials of this procedure require FDA approval and an investigational device exemption due to potential for harms.

EVIDENCE SUMMARY

The following discussion focuses on the investigational indications noted in Criterion III above.

DEEP VEIN THROMBOSIS (DVT)

There are several objectives for treatment of venous thromboembolism including:[3, 4]

- Prevention of pulmonary embolism;
- Restoration of unobstructed blood flow through the thrombosed vein;

- Preservation of venous valve function; and
- Prevention of recurrent thrombosis.

The current standard of treatment for achieving these goals is anticoagulant therapy (i.e., intravenous unfractionated heparin) to achieve a therapeutic partial thromboplastin time (PTT). After completion of an initial course of anticoagulation therapy, patients with venous thromboembolism (VTE) require continuing therapy to prevent recurrence. Thus, anticoagulation therapy is the standard against which PTA with or without stenting must be compared in order to evaluate the safety, efficacy, and final health outcomes. In addition, long-term follow-up is needed to determine the rates of restenosis, device failure, reoperation, and VTE recurrence.

The following literature appraisal is focused on the published evidence for DVT that is not related to left iliac vein compression syndrome or proximal upper extremity venous thrombosis.

Systematic Reviews

No systematic reviews were identified.

Randomized Controlled Trials

There are no randomized controlled clinical trials (RCTs) in which PTA with or without stenting was compared to standard medical management of DVT.

Nonrandomized Studies

- The bulk of the current literature investigating thrombolysis followed by angioplasty and stenting is limited to small (n<50), non-randomized, non-comparative retrospective reviews and case series of short- to medium-term duration.[4-9]
- The majority of studies are for DVT related to extrinsic compression (e.g., May-Thurner syndrome), or have heterogeneous patient populations that include both compression-related and non-compression-related DVT.

IDIOPATHIC INTRACRANIAL HYPERTENSION

Studies for the diagnosis and treatment of idiopathic intracranial hypertension (IIH) must answer the following questions:

1. Is venous sinus occlusion the cause or the effect of increased intracranial pressure (ICP)?
2. Is venous PTA with or without stenting safe and effective in reducing ICP compared with conventional treatment?

To assess the effectiveness and safety of intracranial venous stenting as a treatment of IIH, health outcomes must be compared with current standard treatments. The ideal clinical trial design is random allocation of similar patients to active or sham venous angioplasty, and/or conventional medical or surgical treatments.

Systematic Reviews

Kalyvas (2021) published a systematic review of controlled and observational studies on surgical treatments of IIH, including CSF diversion techniques, optic nerve sheath fenestration, bariatric surgery, and venous sinus stenting.[10] One hundred and nine publications were

included in the review, consisting of three prospective observational studies, 74 retrospective case series, and 31 case reports. No randomized controlled trials were identified for inclusion in the review. Of the 2,302 predominately female (84.3%) patients included across studies, 825 underwent venous sinus stenting. Data specific to venous sinus stenting were from 47 studies, of which three were prospective, 29 were retrospective case series, and 14 were single case reports. Improved papilledema, visual fields and headaches following venous sinus stenting was reported as 87.1%, 72.7% and 72.1% of the patients respectively. Restenting or supplementary intervention was needed due to venography-documented restenosis in 3.4% of patents. Adequate data to generate estimates of 12-month failure rate for venous sinus stenting of 13.1% was available from 20 studies. Major complications were reported in 19 patients (2.3%) including subdural hematoma, intracerebral hematoma, subarachnoid hemorrhage, cerebellar hematoma, obstructive hydrocephalus, and death.

A 2015 updated Cochrane review evaluated the evidence for IIH interventions, and included RCTs in which any intervention used to treat IIH had been compared to placebo or another form of treatment.[11] Stenting of the transverse intracerebral venous sinus was assessed as a treatment, however the reviewers found no studies that met their inclusion criteria due to the lack of a control group for comparison. The review excluded five small case series, one retrospective review and two small clinical trials.

A 2014 systematic review of various treatments for IIH found only case series, of which 30 had extractable data.[12] Of the 332 total patients, 88 had venous sinus stenting. However, the studies only reported secondary outcomes related to symptoms of headache, papilledema, and visual acuity. The primary outcome of increased intracranial pressure was not reported. The authors concluded that the evidence was insufficient to recommend for or against any treatment modalities for IIH.

Randomized Controlled Trials

There are no randomized controlled clinical trials in which PTA with or without stenting was compared to standard medical or surgical management of IIH.

Nonrandomized Studies

Current evidence is limited to mainly small retrospective reviews and case series.[13-16] One of the largest studies was a retrospective review of 52 patients at a single center who underwent stenting due to IIH unresponsive to maximum acceptable medical treatment.[17] The follow-up period ranged from two months to nine years. All 52 patients were reported to have immediate elimination of the transverse sinus stenosis gradient and rapid improvement in IIH symptoms including resolution of papilledema. Six patients had relapse of symptoms (headache) and increased venous pressure with recurrent stenosis adjacent to the previous stent. In these patients, an additional stent was placed, with response similar to that following the first stent placement. Another retrospective study, published by Boddu (2019), included 70 consecutive patients who underwent venous sinus stenting for IIH and reported that 13% of the patients had impaired drainage of the vein of Labbé following treatment.[18]

ILIOFEMORAL VENOUS OBSTRUCTIVE DISEASE

Systematic Reviews

Ferreira (2021) published a systematic review of available data on mid-term (30 days to three years) stent patency rates and clinical outcomes of iliac stenting in post-thrombotic

syndrome.[19] Data from 1008 patients reported in 18 publications were included. The pooled technical success rate was 96%. The pooled primary and secondary patency rates were 98.2% and 100% at 30 days, 78.1% and 94.5% at 12 months and 66.3% and 89.4% at 36 months, respectively. Pooled rates of ulcer healing, pain and edema relief were 78.1%, 53.4% and 48.8%, respectively. Intraoperative venous injury was reported in four studies, with a pooled proportion rate of 28.0% (95% confidence interval [CI] 14.1 to 44.5, I^2=91.4%). The most common minor complication, postoperative back pain, was reported in three studies at a rate of 57.1% (95% CI 46.3 to 67.6, I^2=73.9%). Two studies reported stent fracture at a rate of 5.9% (95% CI 3.1 to 9.4, I^2=18.6%). Stent migration was reported in one study. Bias at the outcome level was evaluated with the GRADE system in 14 of the studies; serious or very serious risk of bias was found in nine of the 14 studies assessed and the quality of all studies assessed was low or very low.

Nonrandomized Studies

A retrospective analysis of forty-two patients (27 women and 15 men with a mean age of 47.3 years) who underwent venous recanalization, pre-dilatation and stenting of the narrowed or occluded iliac and/or femoral veins to treat chronic femoro-iliac venous obstructive disease was published by Guillen (2020).[20] Severity of post-thrombotic syndrome (PTS) and quality of life were assessed at baseline and three months after the intervention respectively, using Villalta score and Chronic Venous Insufficiency Questionnaire (CIVIQ-20) scale. Results: Immediate technical success was achieved in 41/42 (97.6%) patients, without any major complications. Primary patency, primary assisted patency and secondary patency at the end of the median imaging follow-up of 18.1 months (IQR, 9.7 to 34.4) were achieved in 29/42 (66.7%) patients, 33/42 (78.6%) patients and 37/42 (88.1%) patients, respectively. Median Villalta and CIVIQ-20 scores decreased from 14 (IQR, 10 to 19) and 57 (IQR, 39 to 72) at baseline, respectively, to 5 (IQR, 2 to 9) and 30 (IQR, 24 to 50) three months after the procedure, respectively ($p<0.0001$), indicating significant decrease in the severity of PTS and improvement in quality of life. Of note, early in-stent thrombosis within one month occurred in 9/42 (21.4%) patients. This study is limited by its retrospective design, heterogeneity in the stent used, and lack of long-term outcome data.

Results of the VIRTUS trial (VIRTUS Safety and Efficacy of the Veniti Vici Venous Stent System When Used to Treat Clinically Significant Chronic Non-Malignant Obstruction of the Iliofemoral Venous Segment) were published by Razavi (2019).[21] This prospective, international, single-arm, FDA-IDE pivotal study evaluated the safety and effectiveness of a dedicated endovenous stent for symptomatic iliofemoral venous obstruction. One hundred and seventy patients (127 chronic post-thrombotic, mean age 54 years, 56.4% female) at 22 sites were treated with a self-expanding nitinol stent developed for dedicated use in the venous system (Vici Venous Stent System). Patients included those with ≥50% obstruction on venography and Clinical, Etiology, Anatomic, Pathophysiology clinical classification ≥3, or at least moderate leg pain with a Venous Clinical Severity Score of two or greater. Results: Freedom from a major adverse event through 30 days was 98.8%. Through one year, 54 device or procedure-related serious adverse events were reported in 28 (16.5%) of the patients. The one-year primary patency rate for the entire group was 84.0%. Venographic patency rates for the nonthrombotic and chronic post-thrombotic groups were 96.2% and 79.8%, respectively. At 12 months, 64% (85/132) of patients demonstrated at least a three-point reduction in Venous Clinical Severity Score. Long-term (five-year) outcomes are anticipated. This study was funded by both Veniti, Inc. and Boston Scientific, and at least one study author holds financial interest in the sponsoring company.

CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY (CCSVI) IN MULTIPLE SCLEROSIS (MS)

Systematic Reviews

A Cochrane review[22] and five systematic reviews[23-27] with critical analyses of the current literature concluded that there is insufficient evidence to verify a relationship between CCSVI and MS. The authors noted the high degree of heterogeneity between study outcomes, sensitivity, and specificity, and marked variability of odds ratios.

Two meta-analyses[28, 29] reported outcomes after exclusion of outlier studies (e.g., studies with a disproportionately high odds ratio (OR) and/or potential bias). Tsivgoulis (2014) reported on the association between CCSVI and MS and included 19 studies with a total of 1,250 MS patients and 899 healthy controls.[28] When data from all 19 studies were pooled, CCSVI was associated with MS with an OR of 8.35 (95% CI 3.44 to 20.31, p<0.001). However, in additional sensitivity analyses, the OR associating CCSVI and MS decreased. In the most conservative sensitivity analysis, which excluded eight outlier studies, MS was not associated with CCSVI with an OR of 1.35 (95% CI 0.62 to 2.93, p=0.453). The Zwischenberger (2013) meta-analysis of 13 studies with a total of 1141 MS patients and 738 healthy controls reported CCSVI and MS was associated with MS (OR 2.57, p<0.001).[29] In a subsequent analysis of nine studies with four outliers (studies with disproportionately high ORs) removed, the OR decreased, but still associated CCSVI with MS.

A systematic review of the association between CCSVI and MS was published by Laupacis (2011).[26] This review included eight studies that used ultrasound to diagnose CCSVI by the Zamboni criteria and compared the rate of CCSVI in patients with MS to those without MS. These studies were mostly small, with the median number of patients with MS of 50. A large degree of heterogeneity existed across studies in the rate of CCSVI among MS patients. Two smaller studies reported a rate of 0% for CCSVI in a total of 20 and 56 patients with MS. In contrast, the original study by Zamboni (2009a) reported a 100% rate of CCSVI in 109 patients with MS.[30] A small study of 25 patients also reported a very high rate of CCSVI at 84% (21/25). There was no obvious reason identified for this large discrepancy in CCSVI rates; the authors hypothesized that the most likely reason was variability in ultrasound technique and interpretation. The analysis suggested a significant association of CCSVI with MS in combined analysis, with an OR of 13.5 (95% CI, 2.6 to 71.4). A substantial degree of heterogeneity existed in this measure as well, with a reported I2 of 89%. Several sensitivity analyses showed marked variability of the OR from a low of 3.7 to more than 58,000. However, in all cases the association of CCSVI with MS remained significant.

Another systematic review published in 2011 included a smaller number of studies (n=4) but reached conclusions similar to the other analyses.[27] The rate of CCSVI in MS patients ranged from 7% to 100%, and the rate in non-MS patients ranged from 2% to 36%. A significant association was detected between MS and CCSVI but with a high degree of heterogeneity (I^2=96%) and an OR for association that varied widely, from approximately 2 to more than 26,000.

A recently updated Cochrane review evaluated the evidence for PTA to treat CCSVI in patients with MS and included three RCTs, described in greater detail below (total n=238).[31] Two of the studies were judged to be at unclear risk of bias for one item (random sequence generation in one study and blinding in the other), but otherwise at low risk of bias. The authors concluded

that there was moderate-quality evidence that venous PTA did not improve health outcomes for patients with MS and that further study was not necessary.

Randomized Controlled Trials

A randomized wait list study by Napoli (2019) included 66 MS patients with a diagnosis of CCSVI who were randomized to receive venous PTA immediately or after six months.[32] A number of outcomes were assessed, including clinical-functional measures, evoked potentials and upper limb kinematic measures. While there were some statistically significant differences between groups for a composite functional outcome, there were no differences in evoked potential or upper limb kinematic measures.

The following three studies were included in the Cochrane review described above:

Traboulsee (2018) published a double-blind, sham-controlled RCT of balloon venoplasty for MS patients with narrowing of the extracranial jugular and azygos veins.[33] The trial included 104 patients, 49 randomized to venoplasty and 55 to sham treatment, and 103 patients completed the trial with 48 weeks of follow-up. Narrowing of the veins >50% was confirmed by venography prior to randomization. The primary outcome of the trial was change in the MS Quality of Life-54 (MSQOL-54) questionnaire from baseline at 48 weeks. Additional clinical and MRI outcomes were also evaluated. There was no difference found between groups for any of the study's outcomes, and the authors concluded that "for patients with MS, balloon venoplasty of extracranial jugular and azygous veins is not beneficial in improving patient-reported, standardized clinical, or MRI outcomes."

Results from the Brave Dreams trial were published by Zamboni (2018).[34] This was a double-blind, sham-controlled RCT conducted at six MS centers in Italy and included a total of 115 CCSVI patients. These patients were randomized to either venous PTA (n=76) or catheter venography without angioplasty (sham, n=39). There were two primary endpoints assessed at 12 months: the number of new or expanded cerebral lesions by MRI, and a functional measure that included walking control, manual dexterity, balance, postvoid residual urine volume, and visual acuity. There were no significant differences in these endpoints between groups, and no adverse events were reported. The authors concluded that venous PTA was "a safe but largely ineffective technique; the treatment cannot be recommended in patients with MS."

Siddiqui (2014) published results from a prospective, double-blind, sham-controlled RCT of venous angioplasty in MS patients with CCSVI.[35] This trial enrolled nine patients in intervention group and 10 in the sham-controlled group. All patients met the criteria for diagnosis of CCSVI.[36] The primary end points of the trial included safety at 24 hours and 30 days postangioplasty; greater than 75% restoration of venous outflow at 30 days; the presence of new MS lesions; and relapse rate over six months. Secondary end points included changes in disability scores, brain volume, cognitive test scores, and quality-of-life measures. All patients tolerated the procedures well; no operative or postoperative complications were identified. One patient in the angioplasty group experienced an episode of symptomatic bradycardia. No significant differences were observed in venous outflow characteristics between the treated and control groups, nor were any significant improvements observed in clinical disease scores among treated patients compared with controls. The results of this RCT are limited by the small number of patients. However, the failure to show a beneficial effect of venous angioplasty on MS activity supports a lack of efficacy for this treatment.

Nonrandomized Studies

The studies that focused on the potential relationship between CCSVI and MS reported varying and contradictory outcomes. For example, while Zamboni (2009a) and other authors[30, 37-39] reported a strong association between CCSVI and MS, numerous studies have reported insignificant or no difference in the prevalence of CCSVI in MS patients compared to healthy controls, or no association between CCSVI and MS occurrence or symptoms[36, 38, 40-46].

The studies that focused on outcomes of PTA with or without stent placement reported few adverse events, but mixed efficacy outcomes.[47-53] For example, while Zamboni (2009b).[48] reported significant improvement in all measures for patients with relapsing-remitting MS, Kostecki (2011) reported a significant improvement only in heat intolerance and fatigue severity six months post endovascular treatment.[47] No trials were found that compared PTA with concurrent control groups. All authors noted the need for well-designed randomized clinical trials. Many authors asserted that PTA with or without stenting in these patients should not be performed outside the clinical trial setting.

Adverse Events

Burton (2011) described five patients who had undergone venoplasty and presented with complications of the procedure.[54] The complications were internal jugular vein stent thrombosis, cerebral sinovenous thrombosis, stent migration, cranial nerve injury, and injury associated with venous catheterization. There was not a denominator in these studies to determine the rate of these events.

Petrov (2011) reported on the safety profile of 495 venoplasty procedures performed in 461 patients with MS, including 98 stent implantations.[49] There were no deaths, major bleeding events, or acute exacerbations of MS. The most common procedure-related complication was vein dissection, which occurred in 3.0% of cases. Other complications included cardiac arrhythmias (1.2%), groin hematoma (1.0%), vein rupture (0.4%), and acute stent thrombosis (1.6%).

Mandato (2012) reported adverse events within 30 days of endovascular intervention for 240 patients with MS over an 8-month period.[55] Neck pain occurred in 15.6% of patients, most commonly following stent implantation. Headache occurred in 8.2% of patients and was persistent past 30 days in 1 patient (0.4%). Intraprocedural arrhythmias occurred in 1.3%, and one patient was diagnosed with a stress-induced cardiomyopathy following the procedure.

An FDA alert issued in May 2012 reported the potential for adverse events following endovascular interventions for MS.[56] Reports of adverse events obtained by FDA included death, stroke, detachment and/or migration of stents, vein damage, thrombosis, cranial nerve damage, and abdominal bleeding. This alert included the caveat that clinical trials of this procedure require FDA approval and an investigational device exemption because of the potential for harms.

PERCUTANEOUS TRANS-HEPATIC BALLOON AND/OR STENT ANGIOPLASTY

Systematic Reviews

Kyaw (2022) performed a systematic review to determine the efficacy and safety of percutaneous trans-hepatic balloon and/or stent angioplasty in the management of portal vein (PV) stenosis following pediatric liver transplantation.[57] There were 213 pediatric liver recipients who underwent PTA for PV stenosis in 19 included studies published between 1991 and 2019. Balloon angioplasty was the initial treatment in the majority (n=153). Primary stent

placement (n=34) was performed for elastic recoil, intimal tears and PV kinks and rescue stent placement (n=14) for recurrent PV stenosis following primary balloon angioplasty. The technical success was 97.6% to 100% overall, 97.6% to 100% for balloon angioplasty only, and 100% for primary stenting. The clinical success was 50% to 100% overall, 50% to 100% for balloon angioplasty only, and 100% for primary stenting. Long-term PV patency was 50% to 100% overall, 37.5% to 100% for balloon angioplasty only, and 100% for primary stenting. The authors comment that “Stent placement may be a primary option in selected cases and a reliable rescue option for recurrent portal vein stenosis following balloon-angioplasty-only”.

PRACTICE GUIDELINE SUMMARY

DEEP VEIN THROMBOSIS

Two consensus-based clinical practice guidelines from the Society of Interventional Radiology and the American Heart Association, respectively, provided evidence appraisals and noted a benefit in venous stenting for DVT.[58, 59] However, the majority of the references listed were related to May-Thurner syndrome which is caused by extrinsic compression for which stenting is considered medically necessary. Both guidelines graded the available evidence as very limited.

The American Society of Hematology

The American Society of Hematology published a 2020 guideline for the treatment of deep vein thrombosis and pulmonary embolism which does not discuss venous angioplasty or venous stenting.[60]

Society of Vascular Surgery / American Venous Forum

In the 2014 joint guidelines published by Society of Vascular Surgery and American Venous Forum on the management of proximal chronic total venous occlusion/severe stenosis.[61] The guideline states the following:

> *In a patient with inferior vena cava or iliac vein chronic total occlusion or severe stenosis, with or without lower extremity deep venous reflux disease, that is associated with skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we recommend venous angioplasty and stent recanalization in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence.*

This was a grade 1 recommendation (strong) but the evidence was considered low/very low quality which was primarily focused on May-Thurner syndrome.

American College of Radiology (ACR)

ACR Appropriateness Criteria® for radiologic management of lower extremity venous insufficiency recommendation guidelines was updated in 2023 with no change to criterion related to this policy.[62]

The 2012 ACR Appropriateness Criteria® for radiologic management of lower extremity venous insufficiency recommendation did not address angioplasty or stenting for these indications.[62, 63] However, they suggest that patients with venous insufficiency and associated venous occlusion or stenosis of the common iliac vein may require venous recanalization with

angioplasty and stenting as an adjunctive treatment, based on three case reports and one small retrospective analysis.

CHRONIC ILIOFEMORAL VENOUS OBSTRUCTION

Society of Interventional Radiology

A 2023 position statement on the endovascular placement of metallic stents for the management of chronic iliofemoral venous obstruction by the Society of Interventional Radiology (SIR) concluded that "the use of endovascular stent placement for chronic iliofemoral venous obstruction to be likely to help selected patients, but the risks and benefits have not been fully quantified in well-designed randomized studies."[64] They recommended the urgent completion of such studies.

CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY IN MULTIPLE SCLEROSIS (MS)

Society of Interventional Radiology

In 2010 the SIR published a position statement on the association of CCSVI with MS and the efficacy of endovascular treatments.[65] Their recommendations included the following statements:

- At present, SIR considers the published literature to be inconclusive on whether CCSVI is a clinically important factor in the development and/or progression of MS, and on whether balloon angioplasty and/or stent placement are clinically effective in patients with MS.
- SIR strongly supports the urgent performance of high-quality clinical research to determine the safety and efficacy of interventional MS therapies, and is actively working to promote and expedite the completion.

SUMMARY

There is enough research to show that percutaneous venous angioplasty, with or without stenting, can improve health outcomes for people with certain types of venous stenosis. Therefore, this angioplasty may be considered medically necessary for individuals that meet the policy criteria.

There is not enough research to show that percutaneous venous angioplasty, with or without stenting, can improve health outcomes for individuals that do not meet the policy criteria, including those with deep vein thrombosis that is not related to upper extremity venous compression requiring rib resection or iliac vein compression syndrome, or those with chronic cerebrospinal venous insufficiency venous sinus obstruction or occlusion in idiopathic intracranial hypertension. Therefore, this procedure is considered investigational when policy criteria are not met.

REFERENCES

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CODES

Codes	Number	Description
CPT	36481	Percutaneous portal vein catheterization by any method
	37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein
	37239	; each additional vein (List separately in addition to code for primary procedure)
	37248	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein
	37249	;each additional vein (List separately in addition to code for primary procedure)
HCPCS	C2623	Catheter, transluminal angioplasty, drug-coated, non-laser

Date of Origin: *January 1996*