Medical Policy Manual

Topic: Percutaneous Angioplasty and Stenting of Veins

Date of Origin: January 1996

Section: Surgery

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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.

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, nonthrombotic 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 (CCSVI) 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 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 May 2012, the FDA issued an alert concerning the potential for adverse events following endovascular interventions to treat chronic cerebrospinal venous insufficiency (CCSVI).\[^3\] 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 alert included the caveat that clinical trials of this procedure require FDA approval and an investigational device exemption due to potential for harms.

**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 are considered medically necessary. Carotid and intracranial vessels are addressed in separate policies (see Cross References below).

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**MEDICAL POLICY CRITERIA**

I. Percutaneous transluminal angioplasty, with or without stenting, may be considered **medically necessary** for the treatment of venous vascular stenoses in the following instances:

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 vena cava syndrome with significant symptoms, from either extrinsic compression or intrinsic stenosis/occlusion [when standard treatments (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 proximal upper extremity venous thrombosis due to persistent extrinsic compression (Paget-Schroetter syndrome) documented by pre-procedure imaging (i.e., ultrasound, venography, CT, or MRI)
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 for all other venous indications, including but not limited to:
   A. Deep vein thrombosis that is not related to upper extremity venous compression or iliac vein compression syndrome (I.C.-D.) (e.g., inferior vena cava, iliac, lower extremity)
   B. Chronic cerebrospinal venous insufficiency in multiple sclerosis or other conditions
   C. Venous sinus obstruction or occlusion in idiopathic intracranial hypertension

SCIENTIFIC EVIDENCE

The following discussion focuses on the investigational indications noted in III.A-C above.

Deep Vein Thrombosis (DVT)

There are several objectives for treatment of venous thromboembolism including:[4,5]

- 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 percutaneous transluminal angioplasty (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 (RCTs)

There are no randomized controlled clinical trials 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.[5-9]

• 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 noncompression-related DVT.

### Idiopathic Intracranial Hypertension (IIH)

Studies for the diagnosis and treatment of 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

A 2015 updated Cochrane review was conducted to assess interventions for IIH that included RCTs in which any intervention used to treat IIH had been compared to placebo or another form of treatment.[10] 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.[11] 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 small retrospective reviews and case series. All but one of these studies included 18 or fewer subjects.[12-15] The largest study was a retrospective review of 52 patients at a single center who underwent stenting due to IIH unresponsive to maximum acceptable medical treatment.[16] The follow-up period ranged from 2 months to 9 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.
Chronic Cerebrospinal Venous Insufficiency (CCSVI) in Multiple Sclerosis (MS)

Systematic Reviews

A Cochrane review[17] and five systematic reviews[18-22] 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[23,24] reported outcomes after exclusion of outlier studies (e.g., studies with disproportionately high ORs and/or potential bias). Tsivgoulis et al. (2014) reported on the association between CCSVI and MS and included 19 studies with a total of 1250 MS patients and 899 healthy controls.[23] When data from all 19 studies were pooled, CCSVI was associated with MS with an odds ratio (OR) of 8.35 (95% confidence interval [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 8 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 et al. 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).[24] In a subsequent analysis of 9 studies with 4 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 in 2011 by Laupacis et al.[21] This review included 8 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 et al. reported a 100% rate of CCSVI in 109 patients with MS. 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.[22] 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 (I2=96%) and an OR for association that varied widely, from approximately 2 to more than 26,000.

Randomized Controlled Trials (RCT)

In 2014, Siddiqui et al. published results from a prospective, double-blind, sham-controlled randomized clinical trial (RCT) of venous angioplasty in MS patients with CCSVI.[25] This trial enrolled 9 patients in intervention group and 10 in the sham-controlled group. All patients met the criteria for diagnosis of CCSVI.[26] 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 6 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 et al. and other authors\[27-30\] 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\[26,29,31-37\].

The studies that focused on outcomes of PTA with or without stent placement reported few adverse events, but mixed efficacy outcomes.\[38-43\] For example, while Zamboni et al.\[39\] reported significant improvement in all measures for patients with relapsing-remitting MS, Kostecki and colleagues reported a significant improvement only in heat intolerance and fatigue severity 6 months post endovascular treatment.\[38\] 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 et al. described five patients who had undergone venoplasty and presented with complications of the procedure.\[44\] 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 et al. reported on the safety profile of 495 venoplasty procedures performed in 461 patients with MS, including 98 stent implantations.\[40\] 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 et al. reported adverse events within 30 days of endovascular intervention for 240 patients with MS over an 8-month period.\[45\] 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 1 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. 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.

Clinical Practice Guidelines

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.\textsuperscript{[47,48]} 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.

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.\textsuperscript{[49]} The guideline states the following:

\textit{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)

The 2012 ACR Appropriateness Criteria\textsuperscript{®} for radiologic management of lower extremity venous insufficiency recommendation did not address angioplasty or stenting for these indications.\textsuperscript{[50]} 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 Cerebrospinal Venous Insufficiency (CCSVI) in Multiple Sclerosis (MS)

Society of Interventional Radiology (SIR)

In 2010 the SIR published a position statement on the association of CCSVI with MS and the efficacy of endovascular treatments.\textsuperscript{[51]} 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 not enough research to show that percutaneous venous angioplasty with or without stenting improves health outcomes for patients with deep vein thrombosis that is not related to upper extremity venous compression or iliac vein compression syndrome, chronic cerebrospinal venous insufficiency, or venous sinus obstruction or occlusion in idiopathic intracranial hypertension. Many studies have limitations including small sample sizes, lack of an appropriate comparator group, lack of long-term data, and different patient populations. In addition, there are no evidence-based clinical practice guidelines that strongly recommend venous angioplasty with or without stenting for these indications. Therefore, this procedure is considered investigational for all conditions that do not meet the policy medical necessary criteria.

REFERENCES


**CROSS REFERENCES**

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

*Endovascular Angioplasty and/or Stenting for Intracranial Arterial Disease (Atherosclerotic and Aneurysms)*, Medical Policy, Surgery, Policy No. 141

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