

Medical Coverage Policy



Effective Date.....11/15/2020
Next Review Date.....11/15/2021
Coverage Policy Number 0541

Venous Angioplasty and/or Stent Placement in Adults

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Overview

This Coverage Policy addresses venous angioplasty and/or stent placement in adults ≥ 18 years of age. This policy does not address venous angioplasty and/or stent placement in individuals under 18 years of age. Percutaneous revascularization of the lower extremities in adults is addressed in a separate Medical Coverage Policy.

Coverage Policy

Venous angioplasty and/or stent placement in an adult ≥ 18 years of age is considered medically necessary for ANY of the following indications:

- thrombotic obstruction of major hepatic veins (e.g., Budd-Chiari Syndrome)
- iliac or iliofemoral vein intervention for iliac vein compression syndrome (e.g., May-Thurner Syndrome)
- iliac vein or inferior vena cava stenting for obstructive disease, without superficial truncal reflux, in a symptomatic individual with skin or subcutaneous changes, healed or active ulcers (Clinical, Etiology, Anatomy, and Pathophysiology [CEAP] classes 4-6)
- superior vena cava syndrome

- pulmonary vein stenosis
- stenotic or thrombosed arterio-venous-dialysis access grafts
- stenosis associated with central venous catheters or transvenous pacemaker leads
- as an adjunct to catheter-directed thrombolysis for acute femoroiliocaval deep vein thrombosis post thrombolysis for EITHER of the following:
 - when there is significant residual stenosis (50% or more) acutely
 - when subsequent imaging identifies significant residual stenosis in a symptomatic patient

Repeat venous angioplasty and/or stent placement in an adult ≥ 18 years of age is considered medically necessary for ANY of the above indications when there is angiographic evidence of restenosis.

For all other indications venous angioplasty and/or stent placement is considered not medically necessary.

General Background

Angioplasty, and/or vascular stenting, is a minimally invasive procedure that has been performed as an alternative to open vascular surgery to improve blood flow when there is narrowing in the body's veins. The procedure is usually performed in an interventional radiology suite.

In an angioplasty procedure, imaging techniques (typically fluoroscopy) are used to guide a balloon-tipped catheter, a long, thin plastic tube, into a vein and advance across the area of vessel narrowing or blockage. The balloon is inflated to open the vessel, then deflated and removed. Many angioplasty procedures also include the placement of a stent, a small, flexible tube made of plastic or wire mesh to support the damaged artery walls. Stents can be self-expandable (opens up itself upon deployment) or balloon expandable (balloon needed to open the stent). Venous angioplasty may have to be repeated for restenosis or blockage. If a stent is placed, the chance of restenosis is reduced but it can still occur.

There are numerous conditions which have been treated with venous angioplasty and/or stenting, including, but not limited to, iliac vein compression syndrome (May-Thurner syndrome), ilio caval obstruction; stenotic or thrombosed arterio-venous-dialysis access grafts; thrombotic obstruction of major hepatic veins (Budd-Chiari syndrome), superior vena cava syndrome, pulmonary vein stenosis, venous thoracic outlet syndrome, idiopathic intracranial hypertension, Multiple Sclerosis or chronic cerebrospinal venous insufficiency, left iliac vein compression associated with pelvic congestion syndrome and chronically occluded iliac veins.

Thrombotic Obstruction of Major Hepatic Veins (e.g., Budd-Chiari Syndrome)

Budd-Chiari syndrome (BCS) is a rare, life-threatening disorder caused by obstruction of hepatic venous outflow and/or the inferior vena cava. The approach to management in patients with Budd-Chiari syndrome depends on clinical and anatomic features. Radiologically-guided treatment, including angioplasty and stenting, can be used to treat patients with acute or subacute Budd-Chiari syndrome who are symptomatic, provided a venous obstruction amenable to percutaneous angioplasty and stenting is visualized radiologically (e.g., on magnetic resonance venography or percutaneous venography) (Lai, 2020; Zhang and Wang, 2015).

Literature Review: Zhang and Wang (2015) conducted a systematic review with meta-analysis to update and quantitatively assess the successful rate of interventional operation; the rate of vascular restenosis (including vascular re-occlusion) at one year after initial operation; the survival rate at one and five years after initial operation in different types of intervention. Various types of intervention, such as thrombolysis, angioplasty, stent implantation, and transjugular intrahepatic portosystemic shunting (TIPS), have different treatment outcomes for BCS patients. A total of 29 articles on interventional treatment with BCS were included in the meta-analysis, for a total of 2255 BCS patients. The pooled results were 93.7% (92.6–4.8) for successful rate of interventional operation, 6.5% (5.3–7.7%) for restenosis rate of interventional treatment, and 92.0% (89.8–94.3%) and 76.4 % (72.5–80.4%) for the survival rate at one and five years, respectively. The interventional therapy of major BCS patients is safe with successful operation, good patency, and long-term survival. A step-wise management of BCS is proposed to manage and cure all BCS patients with personalized treatment.

Professional Societies/Organizations: American Association for the Study of Liver Diseases (AASLD): The evidence-based AASLD recommendations for therapy of Budd-Chiari syndrome state that the rationale for recanalization has been to decompress the liver without compromising, and even while restoring, hepatic blood flow (DeLeve, et al., 2009). Patients with focal or segmental obstruction of the hepatic venous outflow tract are theoretically eligible for recanalization. The AASLD recommendations state:

- Check for a venous obstruction amenable to percutaneous angioplasty/stenting in all symptomatic patients. Treat accordingly (Class I, Level C).

Grading System for Recommendations:

- Class 1: Conditions for which there is evidence and/or general agreement that a given diagnostic evaluation, procedure or treatment is beneficial, useful, and effective.
- Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

Iliac Vein Compression Syndrome (e.g., May-Thurner Syndrome)

May-Thurner syndrome (MTS) is defined as extrinsic venous compression by the arterial system against bony structures in the ilio caval venous territory. MTS is also referred to as ilio caval venous compression syndrome, iliac vein compression syndrome, Cockett's syndrome, and venous spur. The resultant venous stasis from this compression can lead to venous congestion and the development of deep venous thrombosis (DVT) in the left lower extremity. This syndrome is relatively uncommon. The approach to diagnosis and treatment depends upon whether venous thrombosis is present. If DVT is occurs, it is treated with anticoagulation therapy. When the diagnosis is suspected based upon clinical features or noninvasive vascular imaging, a definitive diagnosis is established using intravascular ultrasound (after removal of thrombus, if necessary). The mechanical compression is treated with surgery or stent placement. Minimally invasive treatment, angioplasty and stenting, of the venous lesion relieves outflow obstruction and provides immediate relief of symptoms with good long-term patency rates. For those with venous thrombosis, rates of post-thrombotic syndrome are reduced with endovascular treatment (Mousa, 2020; Kaltenmeier, et al., 2017).

Literature Review: In a multicenter retrospective study, Funatsu et al. (2019) investigated the efficacy and safety of stent implantation for treating May-Thurner syndrome (MTS) with acute DVT. A total of 59 patients from 10 hospitals in Japan were treated with stents for left iliac vein stenosis with acute DVT. All patients had acute symptomatic DVT involving the left common iliac vein and underwent stent implantation. There were no exclusion criteria except for patient's refusal. The primary endpoint for the study was stent patency. The secondary endpoint was recurrence of DVT and development of post-thrombotic syndrome (PTS) during follow-up. Patient success was achieved in 56 patients (95%). Clinical follow-up was conducted for 50 patients (89%) for a median duration of 40 months (range 8-165 months). A total of 44 patients (79%) were followed up using imaging modalities. During this period, four patients (9%), had stent occlusion and one patient was successfully treated using balloon angioplasty. Primary and secondary patency rates were 84% at 19 months and 93% at 20 months, respectively. Recurrence of DVT was documented in three (8%) of the patients. PTS was evaluated from 36 patients. Three patients (8%) had PTS; however, none of the patients had severe PTS. This study is limited by the small sample size and design of the study.

Kaltenmeier et al. (2018) conducted a systematic review of May-Thurner syndrome (MTS). The authors summarized patients' presentations, diagnostic modalities, and treatment strategies between men and women. The systematic review included 104 articles providing relevant information for 254 patients. Multiple treatment modalities have been used to treat MTS, including endovascular interventions without thrombolysis (53%) or with thrombolysis (33.2%), open surgery (6.8%), and medical management (7%). Endovascular treatment was more common compared with surgical or medical treatment. Before the year 2000, 75% of procedures were performed by open surgery (39/52) and 25% were endovascular (13/52). In contrast, during the following period (2000-2014), 4.1% of treatment involved open surgery (45/1099) and 95.9% (1054/1099) were endovascular interventions. Complications were more common after open compared with endovascular procedures (8.1% vs 3.3%; $p=0.21$). The mean reported follow-up time was 25.8 months, and 20 patients had to undergo reinterventions after open (3.2%; $n=3/94$) or endovascular (1.6%; $n=17/1067$) treatment. The patency of the treated vein after 12 months was superior for endovascular treatment (96% [576/599]) compared with open surgery (64.2% [20/31]; $p<0.01$). Information on follow-up could be extracted from 79 articles, most of them being single case reports or large case series if detailed information was provided. MTS is more common in women, with a ratio of at least 2:1 compared with men. Women with MTS tend to present at a younger age and

have increased risk of PE compared with men. The authors report that the findings support the current paradigm of endovascular therapy as a modality of choice for MTS and iliac vein compression as well.

Moudgill et al. (2009) reported in a review that current management of May-Thurner syndrome (MTS) largely involves endovascular therapy. A review was conducted of six studies containing at least five patients with MTS treated by endovascular therapy. The authors compiled data on 113 patients, analyzing patient demographics, treatment details, and outcome. Review of 113 patients revealed that the majority were females (72%) presenting with DVT (77%), most of which was acute in onset (73%). Therapy consisted of catheter-directed thrombolysis and subsequent stent placement in the majority of patients, resulting in a mean technical success of 95% and a mean 1-year patency of 96%. Endovascular therapy is the current mainstay of treatment for MTS. Review of the current literature supports treatment via catheter-directed thrombolysis followed by stent placement with good early results.

Use Outside of the US: Cardiovascular and Interventional Radiological Society of Europe (CIRSE): CIRSE standards of practice guidelines on ilio caval stenting conclude that stenting in chronic ilio caval obstruction is safe and effective. It provides excellent long-term results with respect to target vessel revascularization as well as symptom relief, therefore improving the quality of life. In selected patients, it appears to even reverse established postthrombotic syndrome (Mahnken, et al., 2014).

Iliocaval Venous Obstruction (ICVO)

Iliocaval venous obstruction (ICVO) is a clinicopathologic condition of the systemic veins of the abdomen that can be due to one of several etiologies and that may contribute to venous hypertension or extensive lower extremity deep vein thrombosis (DVT). Whether to proceed with treatment depends upon the etiology of obstruction, severity of symptoms, and the presence or absence of thrombus (i.e., nonthrombotic ICVO versus thrombotic ICVO). For symptomatic ilio caval venous obstruction (ICVO) stenosis, stenting is preferable but is not universally agreed upon. Stenting is important for maintaining patent venous outflow in the long term. Without stenting, recurrence rates are > 70%. In the iliac segment, residual stenosis has been correlated to the development of post-thrombotic syndrome. Recurrence rates may depend upon underlying pathology and type of stent used. If thrombus is present on the initial venogram, angioplasty and stenting of a stenotic ICVO lesion is performed once thrombus has been cleared. Once vein patency is restored using pharmacomechanical thrombolysis, as confirmed by repeat venography, angioplasty and stenting can be performed (Mousa, et al., 2020).

Professional Societies/Organizations: The 2020 American Venous Forum, the Society for Vascular Surgery, the American Vein and Lymphatic Society, and the Society of Interventional Radiology appropriate use criteria (AUC) for chronic lower extremity venous disease to provide clarity to the application of venous procedures (Masuda, et al., 2020). For iliac vein or inferior vena cava (IVC) obstructive disease, defined as $\geq 50\%$ area reduction by intravascular ultrasound or occlusion and no superficial truncal reflux, the panelists rated stenting as first-line treatment appropriate for symptomatic patients with Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classes 4 to 6. Although most of the evidence consists of case series, guidelines and summaries suggest that stenting for symptomatic venous obstructions for advanced stages (C4b-C6) is beneficial. The panelists state that the results of treating edema seemed less predictable with stenting (see C3, edema), which accounts in part for the rating by the panelists of may be appropriate with or without coexisting superficial truncal reflux. The panelists noted that edema can range from ankle to entire leg and if unilateral would more likely be due to a venous cause. The level of edema below or above the knee is not specified in reports, and its significance in ilio caval disease and how it affects outcomes need further research.

Visible manifestations of venous disorders according to CEAP clinical class (based on revised CEAP classification):

- C0 no visible or palpable signs of venous disease
- C1 telangiectasias or reticular veins
- C2 varicose veins: distinguished from reticular veins by a diameter of ≥ 3 mm
- C3 edema
- C4a pigmentation or eczema
- C4b lipodermatosclerosis or atrophie blanche

- C5 healed venous ulcer
- C6 active venous ulcer

Appropriateness criteria for iliac vein or inferior vena cava (IVC) stenting as first-line treatment:

Appropriate:

- Iliac vein or IVC stenting for obstructive disease without superficial truncal reflux as first-line treatment in a symptomatic patient with skin or subcutaneous changes, healed or active ulcers (CEAP classes 4-6).

Appropriate treatment is a generally acceptable and reasonable approach for the indication. Treatment is likely to improve the patient's health outcomes or survival.

May be Appropriate:

- Iliac vein or IVC stenting for obstructive disease with or without superficial truncal reflux as first-line therapy in a symptomatic patient with edema due to venous disease (CEAP class 3), provided careful clinical judgment is exercised because of the potential for a wide range of coexisting nonvenous causes of edema

May be appropriate treatment may be an acceptable or reasonable approach for the indication or treatment may improve the patient's health outcomes or survival or more research or patient information is necessary to classify the appropriateness of the indication.

Never Appropriate:

- Iliac vein or IVC stenting for obstructive disease in an asymptomatic patient for iliac vein compression, such as May-Thurner compression, for incidental finding by imaging or telangiectasia (CEAP class 1)

Superior Vena Cava Syndrome

Superior vena cava (SVC) syndrome results from any condition that leads to obstruction of blood flow through the SVC. Malignant obstruction can be caused by direct invasion of tumor into the SVC, or by external compression of the SVC by an adjacent pathologic process involving the right lung, lymph nodes, and other mediastinal structures, leading to stagnation of flow and thrombosis. In some cases, both external compression and thrombosis coexist. In addition, patients with malignancy have a higher risk of venous thrombosis related to indwelling venous devices (eg, central venous catheter, pacemaker). The diagnosis of SVC syndrome may be suspected based on characteristic symptoms and signs of thoracic central venous obstruction. Confirmation of a diagnosis of thoracic central venous obstruction requires imaging (Drews, et al., 2019).

Patients with acute SVC syndrome caused by malignant disease are generally treated with intravenous heparin followed by warfarin to prevent recurrence and protect the venous collateral circulation. Symptoms frequently improve after irradiation, chemotherapy, or combination chemoradiation based on the tumor histology. Endovascular treatment with stenting can help achieve rapid symptom resolution in 95% of cases. It is recommended that patients with severe incapacitating symptoms not responding to conservative therapy be considered for interventional treatment, depending on the cause and anatomy of the SVC lesion. Endovascular treatment is now accepted as the first-line treatment in benign and malignant cases. Treatment modalities include percutaneous transluminal balloon angioplasty (PTA), stenting, and thrombolysis performed alone or in combination. Surgical reconstruction is reserved for patients with extensive chronic venous thrombosis not anatomically suitable for endovascular treatment and for those with less extensive disease who have failed prior endovascular treatment (Drews, 2019; Kalra, et al., 2018).

Pulmonary Vein Stenosis

Pulmonary vein stenosis (PVS) is an uncommon entity (estimated incidence about 2-3 cases per year in large centers). Morbidity and mortality rates are high at advance stages. The condition, linked in the past to congenital heart diseases in childhood and mediastinal processes (i.e., tumors) in adults, is now firstly associated to injury from radiofrequency ablation for atrial fibrillation. PVS is characterized by a progressive lumen size reduction of one or more pulmonary veins that, when hemodynamically significant, may raise lobar capillary pressure leading to signs and symptoms such as shortness of breath, cough, and hemoptysis. Image techniques (transesophageal echocardiography, computed tomography, magnetic resonance and perfusion imaging) are used to reach a final diagnosis and decide an appropriate therapy. (Pazos-López, et al., 2016).

Transcatheter therapy is the most common chosen approach for PVS in adults. While evidence of treatment of PVS due to extrinsic compression, infiltration or cardiac surgery is restricted to cases reports in literature several small studies have evaluated the efficacy of percutaneous interventions for PVS after radiofrequency ablation (Pazos-López, et al., 2016). There have been published reports of venous angioplasty being successfully used to treat pulmonary vein stenosis following lung transplant (Loyalka, 2012).

Literature Review: In a single-center retrospective study, Schoene et al. (2018) analyzed catheter interventional treatment of radiofrequency-induced pulmonary vein stenosis (PVS) following atrial fibrillation (AF) ablation. The total rate of PVS following interventional AF ablation was 0.78% (87 of 11,103). Thirty-nine patients with PVS were treated with 84 catheter interventions: 68 (81%) with percutaneous transluminal balloon angioplasty (PTA) and 16 (19%) with stent implantation. The distribution of stent type was 3 drug eluting stents (19%) and 13 bare-metal stents (81%). The overall restenosis rate was 53% after PTA versus 19% after stent implantation ($p=0.007$) after a median follow-up period of 6 months (interquartile range: 3 to 55 months). The total complication rate for PTA was 10% versus 13% for stenting ($p=NS$). Despite the lack of randomized studies, the present data and currently available published studies seem to favor stent implantation as a first-line therapy in patients with radiofrequency-induced severe PVS.

In the largest available prospective, observational study ($n=124$) Fender et al. (2016) evaluated the presentation of severe PVS, and examined the risk for restenosis after intervention using either balloon angioplasty (BA) alone or BA with stenting. All 124 patients were identified as having severe PVS by computed tomography in 219 veins. One hundred two patients (82%) were symptomatic at diagnosis. The most common symptoms were dyspnea (67%), cough (45%), fatigue (45%), and decreased exercise tolerance (45%). Twenty-seven percent of patients experienced hemoptysis. Ninety-two veins were treated with BA, 86 were treated with stenting, and 41 veins were not treated. A 94% acute procedural success rate was observed and did not differ by initial management. Major procedural complications occurred in 4 of the 113 patients (3.5%) who underwent invasive assessment, and minor complications occurred in 15 patients (13.3%). Overall, 42% of veins developed restenosis including 27% of veins ($n=23$) treated with stenting and 57% of veins ($n=52$) treated with BA. The 3-year overall rate of restenosis was 37%, with 49% of BA-treated veins and 25% of stented veins developing restenosis ($p<0.001$). Three individuals were lost to follow-up. This study was limited by the study design and this study did not address assessment or treatment of PV restenosis.

Professional Societies/Organizations: The 2017 Heart Rhythm Society (HRS)/ European Heart Rhythm Association (EHRA)/ European Cardiac Arrhythmia Society (ECAS) Asia Pacific Heart Rhythm Society (APHRS)/ Latin American Society of Cardiac Stimulation and Electrophysiology (SOLAECE) expert consensus statement on catheter and surgical ablation of atrial fibrillation states that pulmonary vein (PV) stenosis is defined as a reduction of the diameter of a PV or PV branch. PV stenosis can be categorized as mild 50%, moderate 50%–70%, and severe 70% reduction in the diameter of the PV or PV branch. A severe PV stenosis should be considered a major complication of AF ablation. The incidence of PV stenosis is $<1\%$. Selected treatment options include angioplasty, stent or surgery. For symptomatic patients, PV angioplasty should be considered. Successful PV angioplasty or stenting usually results in a significant relief of symptoms.

Arterio-Venous Dialysis Access Grafts (stenotic or thrombosed)

Vascular stenosis is most often the cause behind hemodialysis vascular access dysfunction. Percutaneous transluminal angioplasty (PTA) remains the gold standard treatment for vascular stenosis (Beathard, 2020; Kouvelos, et al., 2018; El Kassem, et al., 2015; National Kidney Foundation [NKF], 2006).

Literature Review: Kouvelos et al. (2018) assessed the outcomes of plain balloon angioplasty versus stenting for the treatment of failed or malfunctioning chronic hemodialysis arteriovenous grafts (AVGs). A total of eight studies ($n=1051$ patients) were included in this systematic review and meta-analysis. Balloon angioplasty alone was used in 521 patients (49.6%) and stenting in 530 patients (50.4%). At the time of the endovascular re-intervention, the mean life of AVGs was 807.7 ± 115.4 days for the balloon angioplasty and 714.2 ± 96.3 days for the stenting group ($p=0.92$). All AVGs were located in the arm. Most procedures (98.1%) were performed across the venous anastomosis, while 88% of the patients in the stenting group received a stent graft. The technical success rate was significantly higher in the stenting group ($p<0.001$). At 12 months, loss of primary and secondary patency was significantly higher in patients undergoing plain balloon angioplasty compared with stenting ($p<0.001$, and $p=0.008$, respectively).

Professional Societies/Organizations: The National Kidney Foundation (NKF) (2006) clinical practice guidelines for vascular access for the treatment of arteriovenous graft (AVG) complications recommendations:

Treatment of stenosis without thrombosis:

Stenoses that are associated with AVGs should be treated with angioplasty or surgical revision if the lesion causes a greater than 50% decrease in the luminal diameter and is associated with the following clinical/physiological abnormalities:

- abnormal physical findings (B)
- decreasing intragraft blood flow (<600 mL/min) (B)
- elevated static pressure within the graft (B)

If angioplasty of the same lesion is required more than 2 times within a 3-month period, the patient should be considered for surgical revision if the patient is a good surgical candidate.

If angioplasty fails, stents may be useful in the following situations:

- surgically inaccessible lesion (B)
- contraindication to surgery (B)
- angioplasty-induced vascular rupture (B)

Treatment of thrombosis and associated stenosis:

Each institution should determine which procedure, percutaneous thrombectomy with angioplasty or surgical thrombectomy with AVG revision, is preferable based upon expediency and physician expertise at that center.

- Treatment of AVG thrombosis should be performed urgently to minimize the need for a temporary HD catheter. (B)
- Treatment of AVG thrombosis can be performed by using either percutaneous or surgical techniques. Local or regional anesthesia should be used for the majority of patients. (B)
- The thrombectomy procedure can be performed in either an outpatient or inpatient environment. (B)
- Ideally, the AVG and native veins should be evaluated by using intraprocedural imaging. (B)
- Stenoses should be corrected by using angioplasty or surgical revision. (B)
- Methods for monitoring or surveillance of AVG abnormalities that are used to screen for venous stenosis should return to normal after intervention. (B)

The “B” rating indicates “it is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.”

Deep Vein Thrombosis (DVT): DVT refers to the formation of blood clots in deep veins, usually of the lower or upper extremities. Post thrombotic syndrome (PTS), the most common long-term complication of DVT, occurs in a limb previously affected by DVT. Lower extremity DVT is treated primarily medically with anticoagulation, but endovascular treatment is an option for patients with proximal venous thrombosis defined as being at the level of the common femoral vein or higher. Thrombosis at this site occurs in about one third of all cases of lower extremity DVT and obstructs venous return from the lower limb. Proximal DVT occurs more frequently in the left leg as a result of compression of the left iliac vein by the overlying right iliac artery (May-Thurner syndrome). Acute severe proximal deep venous occlusion, characterized by a blue limb, pain, and limb ischemia (phlegmasia cerulea dolens) is often associated with malignancy. Chronic PTS occurs over several years in about half the patients with iliofemoral DVT and involves limb swelling, heaviness, and pain. Medical treatment includes compression stockings and anticoagulation. Endovascular treatment of proximal DVT by catheter-directed thrombolysis with or without balloon angioplasty and self-expanding stents reduces the incidence of post-thrombotic syndrome by about 20% (Kinlay, et al., 2019).

Professional Societies/Organizations: The American College of Phlebology (ACP) Guidelines Committee was developed to assess medical literature and make recommendations to help physicians make evidence-based decisions for the benefit of patients with venous disorders. The grade of recommendation for or against a specific diagnostic or therapeutic intervention may be strong (1) or weak (2), based upon the risk:benefit ratio. The quality of evidence may be rated as high (A),

medium (B), or low (C). The 2015 ACP practice guideline for management of obstruction of the femoroiliocaval venous system recommends venous balloon angioplasty and stenting for the following:

- treatment of non-thrombotic and post-thrombotic iliac and common femoral venous obstructions in patients with lower extremity pain or edema affecting quality of life (QOL) not palliated by compression and for patients with impending or active lower extremity venous leg ulceration (Grade 1B)
- treatment of non-thrombotic and post-thrombotic inferior vena cava (IVC) obstructions in patients with lower extremity pain or edema affecting QOL not palliated by compression and for patients with impending or active lower extremity venous leg ulceration (Grade 1C)
- as an adjunct to catheter-directed thrombolysis for acute femoroiliocaval deep vein thrombosis in order to maintain vein patency and flow when a residual stenosis is found on post thrombolysis imaging (Grade 1B)
- for treatment of non-thrombotic and postthrombotic iliac venous obstructions in patients with chronic pelvic pain, deep dyspareunia, or low back pain which severely affect the QOL when other likely causes have been excluded and the severity of the iliac vein obstruction is considered sufficient to explain the symptoms (Grade 1C)

These ACP recommendations do not address other generally accepted uses of venous balloon angioplasty/stenting such as for dialysis access outflow obstructions, superior vena cava syndrome, Budd-Chiari syndrome, or stenosis associated with central venous catheters or transvenous pacemaker leads (ACP, 2015).

The American Heart Association Scientific Statement on the management of massive and submassive pulmonary embolism, iliofemoral deep vein thrombosis, and chronic thromboembolic pulmonary hypertension states that percutaneous transluminal venous angioplasty and stent placement have been used routinely concomitant with endovascular or surgical thrombus removal to treat obstructive lesions and prevent rethrombosis in patients with acute iliofemoral deep vein thrombosis (IFDVT). Specifically, the finding of a left common iliac vein stenosis in association with left-sided IFDVT, known as iliac vein compression syndrome (May-Thurner syndrome, Cockett syndrome), typically has been treated with stent placement in catheter-directed thrombolysis (CDT) studies (Jaff, et al., 2011).

Recommendations for Percutaneous Transluminal Venous Angioplasty and Stenting state:

- Stent placement in the iliac vein to treat obstructive lesions after catheter-directed thrombolysis (CDT), pharmacomechanical (PCDT), or surgical venous thrombectomy is reasonable (Class IIa; Level of Evidence C).
- For isolated obstructive lesions in the common femoral vein, a trial of percutaneous transluminal angioplasty without stenting is reasonable (Class IIa; Level of Evidence C).
- The placement of iliac vein stents to reduce post-thrombotic syndrome (PTS) symptoms and heal venous ulcers in patients with advanced PTS and iliac vein obstruction is reasonable (Class IIa; Level of Evidence C)

The American Heart Association published a Scientific Statement for postthrombotic syndrome: evidence-based prevention diagnosis, and treatment strategies (Kahn, et al., 2014).

Recommendations for thrombolysis and endovascular approaches to acute DVT for the prevention of postthrombotic syndrome (PTS):

- Catheter-directed thrombolysis (CDT) and pharmacomechanical CDT (PCDT), in experienced centers, may be considered in select patients with acute (≤ 14 days) symptomatic, extensive proximal DVT who have good functional capacity, ≥ 1 -year life expectancy, and low expected bleeding risk (Class IIb; Level of Evidence B).
- Systemic anticoagulation should be provided before, during, and after CDT and PCDT (Class I, Level of Evidence C).

- Balloon angioplasty with or without stenting of underlying anatomic venous lesions may be considered after CDT and PCDT as a means to prevent rethrombosis and subsequent PTS (Class IIb; Level of Evidence B).
- When a patient is not a candidate for percutaneous CDT or PCDT, surgical thrombectomy, in experienced centers, might be considered in select patients with acute (≤ 14 days) symptomatic, extensive proximal DVT who have good functional capacity and ≥ 1 - year life expectancy (Class IIb; Level of Evidence B).
- Systemic thrombolysis is not recommended for the treatment of DVT (Class III; Level of Evidence A).

The AHA guideline states that surgical or endovascular procedures to treat appropriately selected patients with PTS have the potential to decrease postthrombotic morbidity attributable to deep venous obstruction or venous valve incompetence. However, well-designed studies have not been performed because experience with these procedures is limited and only the most severely affected patients are treated. Open surgical and endovenous procedures that correct central postthrombotic venous occlusion or infrainguinal venous valvular incompetence may be offered to patients with severe PTS in an attempt to reduce postthrombotic morbidity and to improve quality of life (QoL). However, Level of Evidence A data do not exist; therefore, only weak recommendations (mostly Level of Evidence C) can be made.

Recommendations for endovascular and surgical treatment of PTS

- For the severely symptomatic patient with iliac vein or vena cava occlusion, surgery (e.g., femoro-femoral or femoro-caval bypass) (Class IIb; Level of Evidence C) or percutaneous endovenous recanalization (eg, stent, balloon angioplasty) may be considered (Class IIb; Level of Evidence B).
- For severely symptomatic patients with postthrombotic occlusion of their common femoral vein, iliac vein, and vena cava, combined operative and endovenous disobliteration may be considered (Class IIb; Level of Evidence C).
- For severely symptomatic patients with PTS, segmental vein valve transfer or venous transposition may be considered (Class IIb; Level of Evidence C).

The AHA guideline discusses upper-extremity DVT (UEDVT) stating that it comprises DVT of the subclavian, axillary, or brachial veins. Although PTS develops after UEDVT, reported incidences are variable, in part because there is no accepted standard for its diagnosis. There is a paucity of data to guide the management of upper-extremity PTS. There have been no trials of compression sleeves or bandages to prevent or treat upper-extremity PTS. Similarly, it is uncertain whether thrombolysis or endovascular or surgical treatment of UEDVT results in lower rates of PTS than standard anticoagulation. Because of a lack of studies on compression bandages, compression sleeves, or venoactive drugs to prevent or treat PTS after UEDVT, it is not possible to make specific recommendations on the prevention or treatment of upper-extremity PTS (Kahn, et al., 2014).

The Society of Vascular Surgery and American Venous Forum published a clinical practice guideline on early thrombus removal strategies for acute deep vein thrombosis (Meissner, et al., 2012). The authors' states that anticoagulant treatment of acute deep venous thrombosis (DVT) has been historically directed toward the prevention of recurrent venous thromboembolism. Anticoagulant treatment imperfectly protects against late manifestations of the postthrombotic syndrome. By restoring venous patency and preserving valvular function, early thrombus removal strategies can potentially decrease postthrombotic morbidity. Evidence-based recommendations are based on a systematic review and meta-analysis of the relevant literature, supplemented when necessary by less rigorous data. Recommendations are made according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, incorporating the strength of the recommendation (strong: 1; weak: 2) and an evaluation of the level of the evidence (A to C).

The guideline states that "on the basis of the best evidence currently available, we recommend against routine use of the term "proximal venous thrombosis" in favor of more precise characterization of thrombi as involving the iliofemoral or femoropopliteal venous segments (Grade 1A). We further suggest the use of early thrombus removal strategies in ambulatory patients with good functional capacity and a first episode of iliofemoral DVT of < 14 days in duration (Grade 2C) and strongly recommend their use in patients with limb-threatening ischemia due to iliofemoral venous outflow obstruction (Grade 1A). We suggest pharmacomechanical strategies over catheter-directed pharmacologic thrombolysis alone if resources are available and that surgical thrombectomy be

considered if thrombolytic therapy is contraindicated (Grade 2C). The authors conclude that most data regarding early thrombus removal strategies are of low quality but do suggest benefits for the patient with respect to reducing postthrombotic morbidity”.

The Society of Vascular Surgery and American Venous Forum published joint guidelines in 2014 on the management of proximal chronic total venous occlusion/severe stenosis (O'Donnell, et al., 2014). The guideline 6.14: proximal chronic total venous occlusion/severe stenosis with skin changes at risk for venous leg ulcer (C4b), healed (C5) or active (C6) venous leg ulcer-endovascular repair 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 (Grade 1: Level of Evidence C).

This was a grade 1 recommendation (strong) but the evidence was considered low/very low quality. The guideline states that in general, quality of the evidence available to support recommendations for endovascular management is mostly limited to level C evidence because of an absence of comparative prospective randomized controlled trials of treatment techniques.

The 2012 American College of Radiology (ACR) Appropriateness Criteria® for radiologic management of lower extremity venous insufficiency variant recommendations do not address angioplasty or stenting as a treatment/procedure for lower extremity venous insufficiency. However, they suggest in the adjunctive treatments section of the document 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. This is based on three case reports and one small retrospective analysis (n=39).

Other Indications

Venous angioplasty and/or stent placement has been proposed for use in a number of indications including, but not limited to, idiopathic intracranial hypertension (IIH), left iliac vein compression associated with pelvic congestion syndrome, Multiple Sclerosis or chronic cerebrospinal venous insufficiency, and venous thoracic outlet syndrome (vTOS). Most of the evidence in the peer-reviewed literature for these indications consists of case series. The studies are limited by lack of a comparator and small sample size therefore conclusions about safety and efficacy cannot be made at this time.

Idiopathic Intracranial Hypertension (IIH): Idiopathic intracranial hypertension (IIH), also known as pseudotumor cerebri and benign intracranial hypertension, is a rare disorder characterized by increased intracranial pressure (ICP) without an intracranial mass. The incidence of IIH is approximately 1 per 100,000 persons. The disorder is primarily found in women during their childbearing and/or peak earning years. Obesity is a risk factor. The cause of this condition is not fully understood but it is associated with diminished resorption of cerebral spinal fluid (CSF). The most common symptoms are headache, visual disturbance and tinnitus. Papilledema is present in at least 95% of the individuals. Diagnosis of IIH includes measurement of ICP, along with examination by a neuro-ophthalmologist for assessment for papilledema, visual acuity, optical coherence tomography, visual field testing, and magnetic resonance venography and angiography. The first-line medical treatments for IIH are lifestyle and pharmacological interventions. The standard medical treatments include weight loss, acetazolamide, diuretics, and repeat high-volume lumbar punctures. Medical treatment generally consists of a combination of carbonic anhydrase inhibitors such as topiramate or acetazolamide, to decrease cerebral spinal fluid (CSF) production, and symptomatic treatment for headache. For medically refractory patients, standard surgical strategies include CSF diversion with ventriculoperitoneal or lumboperitoneal shunts (VPS or LPS) and optic nerve sheath fenestration (ONSF). At one-year and three-year follow-up, ONSF has failure rates of 34% and 45%, respectively. VPS and LPS carry significant infectious/revision rates of 30% and 60%, respectively. Although the underlying pathophysiology of IIH has yet to be fully defined, a number of recent investigations have implicated stenosis of the dural venous sinuses as a potential contributor to the syndrome of IIH in a subset of patients. It has been proposed that venous sinus stenting of the stenotic dural venous sinus may represent a therapeutic option for medically refractory IIH. Venous sinus stenting is a novel treatment and is

not used as a first-line treatment; thus, the current data are in medically refractory IIH patients (Hayes, 2020; Daggubati, et al., 2019; Satti, et al., 2015; Fields, et al., 2011).

Literature Review: There are no randomized controlled clinical trials in which percutaneous angioplasty with or without stenting was compared to standard medical or surgical management of IIH. Current evidence in the peer-reviewed medical literature is limited to small prospective and retrospective reviews and case series. Current data suggest high efficacy and safety of stent placement and lower repeat-procedure rates compared with optic nerve sheath fenestration (ONSF) and cerebral spinal fluid (CSF) shunting. In a cohort of patients, Patsalides et al. (2019) reports a decrease in cerebrospinal fluid opening pressure in patients with IIH three months after venous sinus stenting (VSS), independent of acetazolamide usage or weight loss. While the current evidence appears promising regarding VSS in a subset of patients with IIH, further studies are necessary comparing its efficacy to CSF diversion and ONSF, and establishing the best candidates for stent placement, thus creating specific best-practice guidelines for the treatment of medically refractory IIH. A search of the Clinical trials.gov database yielded active studies evaluating venous sinus stenting for the treatment of IIH (Patsalides, et al., 2019; Giridharan, et al., 2018; Shazly, et al., 2018; Saber, et al., 2018; Matloob, et al., 2017; Piper, et al., 2015; Starke, et al., 2015; Lai, et al., 2014).

Nicholson et al. (2019) conducted a systematic review and meta-analysis evaluating the use of venous sinus stenting (VSS) in individuals with IIH. The systematic review included 20 studies from 18 centers with a total of 474 individuals. Of the 20 studies, 14 were retrospective and six were prospective observational with 6- 52 participants. All of the studies were performed at a single center. Eighty-eight percent of the participants were female. The mean age of the patients was 35, and the mean body mass index (BMI) was 35 kg/m². The mean follow-up period was 18 months (range: <1 month to 198 months). The overall rate of improvement in papilloedema was 93.7%. The overall rate of improvement or resolution of headache was 79.6%. The meta-analysis had positive results including an overall rate of recurrence of IIH symptoms after stenting of 9.8% (95% CI, 6.7% to 13%) and a rate of major complications of 1.9% (95% CI, 0.07% to 3.1%). The rate of recurrence of symptoms requiring a second invasive procedure was 12% after VSS. This appears to be much lower than the 43% retreatment rate observed after CSF diversion procedures. These recurrences were treated with another stent in 72.8% of those patients, while a CSF diversion procedure was performed in 27.2%. The reported limitations to these results include small sample sizes, no comparator group or randomization in the included studies and no standardized tool for clinical evaluation of headache in the included studies.

Saber et al. (2018) conducted a systematic review and meta-analysis to determine clinical outcomes as well as stent survival and stent-adjacent stenosis rates in patients undergoing dural venous sinus stenosis (DVSS) for the management of medically refractory IIH. A total of 473 patients were included from 24 studies. Headache was present in 429 (91.8%) patients and resolved or improved in 319/413 (77.2%) after the procedure. Headache, papilledema, visual acuity, and tinnitus improved in 256/330 (77.6%), 247/288 (85.8%), 121/172 (70.3%), and 93/110 (84.5%) patients following DVSS at the final follow-up (mean of 18.3 months). In a meta-analysis of 395 patients with available follow-up data on stenting outcome (mean of 18.9 months), the stent survival and stent-adjacent stenosis rates were 84% (95% confidence interval [CI] 79-87%) and 14% (95% CI 11-18%), respectively. The rate of major neurological complications was less than 2%. Reported limitations included criteria for enrollment of eligible patients were not similar in all studies. Most included studies were case series or had a small number of participants. Publication bias is a major concern given the fact that series with less desirable surgical outcomes may be less likely to be reported and/or published. Additionally, most studies did not report CSF pressures after venous stenting or at follow-up visits.

Satti et al. (2015) conducted a meta-analysis of optic nerve sheath fenestration, CSF shunting, and dural venous sinus stenting for medically refractory IIH comparing these interventions with a focus on symptom improvement, complications, and the need for repeat procedures. The studies included in this meta-analysis comprised case series and individual case reports. There are no prospective randomized controlled studies. Optic nerve sheath fenestration analysis included 712 patients. The mean follow-up period was 21 months (range, 0–160 months). Post-procedure, there was improvement of vision in 59%, headache in 44%, and papilledema in 80%; 14.8% of patients required a repeat procedure with major and minor complication rates of 1.5% and 16.4%, respectively. The CSF diversion procedure analysis included 435 patients. The mean follow-up time was 41 months (range, 1–278 months). Post-procedure, there was improvement of vision in 54%, headache in 80%, and papilledema in 70%; 43% of patients required at least one additional surgery. The major and minor complication rates were

7.6% and 32.9%, respectively. The dural venous sinus stenting analysis included 136 patients. The mean follow-up time was 22.9 months (range, 1–136 months). After intervention, there was improvement of vision in 78%, headache in 83%, and papilledema in 97% of patients. The major and minor complication rates were 2.9% and 4.4%, respectively. Fourteen additional procedures were performed with a repeat procedure rate of 10.3%. Three patients had contralateral stent placement, while eight had ipsilateral stent placement within or adjacent to the original stent. Only three patients required conversion to CSF diversion or 2.2% of patients with stents.

Piper et al. (2015) conducted an updated Cochrane review to assess interventions for idiopathic intracranial hypertension (IIH) that included randomized controlled trials in which any intervention used to treat IIH had been compared to placebo or another form of treatment. Stenting of the transverse intracerebral venous sinus was assessed as a treatment. 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.

Lai et al. (2014) conducted a systematic review of various treatments for IIH. The reviewers found only case series studies, of which 30 had extractable data. A total of 88 of the 332 total patients had venous sinus stenting. The studies only reported secondary outcomes related to symptoms of visual acuity, headache, and papilledema. 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.

Fargen et al. (2019) conducted a literature review to identify all reports of venous sinus stenting (VSS) in patients with IIH and to synthesize the literature into recommendations for the selection and treatment of patients with IIH with VSS. The authors state that VSS for patients with IIH with venous sinus stenosis is an established and effective treatment option. Venous sinus stenting has been associated with significant symptomatic improvement. Systematic reviews and meta-analyses have been conducted to evaluate symptom improvement in patients following venous sinus stenting. These studies demonstrated 78–83% improvement in headache, 87–97% improvement in papilledema, 74–85% improvement in visual symptoms, and 95% improvement in tinnitus following stenting. The reported complication rates associated with stenting vary in the literature but are low, with an overall complication rate of 1.4–7.4% (major complications 1.6–2.9% and minor complications 1.6–4.4%). Recurrence of symptoms and stent adjacent stenosis can occur following stenting. Two meta-analyses report repeat procedure rates of approximately 10%. Other studies suggest retreatment rates ranging from 0–20%.

Giridharan et al. (2018) published a proposed flow-chart algorithm for treatment and management of medically refractory IIH. For patients with IIH who do not tolerate or experience persistence of symptoms despite maximal medical management, several interventions exist. As part of the proposed initial workup for IIH, patients would have a magnetic resonance venography (MRV) to assess for venous sinus stenosis. For those patients who have evidence of venous sinus stenosis on MRV, persistent headaches, and elevated opening pressures objectively measured by lumbar puncture, with or without visual changes, the provider would consider consulting an endovascular expert to discuss the option of venous sinus stenting (VSS) as a treatment. If after VSS, the patient experiences resolution of headache and stable vision, then long-term follow-up can be continued. If the patient's vision continues to deteriorate, then cerebral spinal fluid (CSF) diversion should be considered as the next therapeutic option. For those patients who have no evidence of venous sinus stenosis on MRV and persistent headaches and high opening pressure, with or without vision changes, we recommend CSF flow diversion as the most appropriate surgical option. In all patients with acute visual changes and grade II papilledema, the recommendation are to proceed with optic nerve sheath fenestration (ONSF). If the patient's visual complaints remain stable, continued long-term follow-up is recommend. If visual complaints persist after ONSF for patients with evidence of venous sinus stenosis on MRV, practitioners should consider a trial of VSS. If VSS is selected as the therapeutic option and fails to control visual changes, CSF flow diversion can alternatively be offered to the patient for symptomatic relief. For those patients with acute visual changes whose symptoms are not relieved by ONSF and who have no evidence of venous sinus stenosis on MRV, the recommendation is CSF flow diversion. The authors state that although the current evidence appears promising regarding VSS in a subset of patients with IIH, additional studies are needed, with a focus on investigating the long-term outcomes for VSS, comparing its efficacy to CSF diversion and ONSF, and establishing the best candidates for stent placement, thus creating specific best-practice guidelines for the treatment of medically refractory IIH.

Recent textbook literature states that acetazolamide combined with a weight loss program is more efficacious for individuals with idiopathic intracranial hypertension and mild to moderate visual loss than is placebo. Any underlying secondary cause should also be treated (e.g., stopping an offending medication, treatment of sleep apnea). Weight loss is beneficial in obese patients. If visual loss progresses, surgical procedures are considered. Optic nerve sheath fenestration allows cerebral spinal fluid to escape through slits or windows in the orbit; sometimes the treatment of one side decreases the optic disc swelling on the other side as well. Complications include visual loss or diplopia. Visual fields are followed carefully to anticipate and prevent visual loss. Lumbar or ventricular peritoneal diversion procedures also reduce intracranial pressure. Their complications include infection and shunt obstruction. Venous sinus stenting has occasionally been used for fixed stenosis (Digre, 2020).

In a 2020 UptoDate document on Idiopathic intracranial hypertension (pseudotumor cerebri): prognosis and treatment, the authors states that venous sinus stenting is a relatively new and somewhat controversial treatment option for IIH. The authors note that further documentation of clinical benefit from venous stenting is required before this becomes a routine part of IIH treatment (Lee, et al., 2020).

Professional Societies/Organizations: No professional society clinical guidelines or recommendations were found for venous sinus stenting in patients with IIH.

Use Outside of the US: A 2018 international consensus guideline on management of idiopathic intracranial hypertension (IIH) in adults states there is uncertainty for the role of neurovascular stenting in acute IIH to prevent loss of vision. The literature consists of observational and case series studies. There is no long-term data regarding efficacy and safety. The role of neurovascular stenting in IIH to preserve rapidly deteriorating vision is not yet established due to a paucity of quality data in this area. It may be useful for highly selected patients with IIH with venous sinus stenosis with an elevated pressure gradient and elevated intracranial pressure in whom traditional therapies have not worked. The consensus guideline states that neurovascular stenting is not currently a treatment for headache in IIH. The literature detailing stenting does not clearly separate the cohorts of IIH into those with visual loss, those with headaches alone and those with both. The literature does not separate those with acute IIH, those with chronic IIH and those with IIH in ocular remission. Another major limitation is that case series are non-randomized; typically, they do not detail morphological stenosis type; they tend to be small in size with selection bias, and there is a lack of long-term follow-up (Mollan, et al., 2018).

Left Iliac Vein Compression Associated with Pelvic Congestion Syndrome (PCS): PCS may be a cause of chronic pelvic pain and results from incompetent valves in the ovarian veins resulting in reflux into pelvic veins, which dilate and become tortuous, forming pelvic varices. Venous obstruction, such as a retroaortic left renal vein, compression of the left renal vein by the superior mesenteric artery (nutcracker syndrome), or left iliac vein compression by the right internal iliac artery (May-Thurner syndrome), as well as hormonal factors may contribute to the development of painful pelvic varicosities. Patients most commonly present between the ages of 20 and 40 years with dull pelvic pain, ache, pressure, or heaviness made worse after prolonged periods of standing, while lifting, or during the premenstrual period. Other risk factors include multiparity, retroverted uterus, and pelvic surgery. Sonography is the first-line imaging choice for assessment of chronic pelvic pain, and PCS may be considered if other more common causes such as endometriosis and leiomyomas have been ruled out. Sonographic findings include multiple dilated veins adjacent to the ovaries and uterus, measuring greater than 5 mm in diameter, and dilated (>5 mm) arcuate veins (especially if observed to cross the myometrium and connect to the pelvic varicosities). Dilatation of the ovarian veins more than 6 mm with retrograde flow is a more specific finding. Treatment options for PCS, bilateral ovarian vein embolization with or without direct sclerotherapy of the pelvic varices is described as the current favored treatment approach. Stent placement may be performed for obstructing anatomic abnormalities. Endovascular approaches to primary ovarian and internal iliac venous reflux have largely supplanted medical and surgical approach (Meissner, et al., 2019; Bennett, 2017).

There is insufficient evidence in the peer reviewed published literature regarding the long term outcomes, safety and efficacy of stent placement performed to relieve left iliac vein compression associated with pelvic congestion syndrome. Available studies have primarily been in the form of case series with small patient population and

short-term follow-up (Huang, et al., 2018; Daugherty, et al., 2015; Asciutto, et al., 2009; Hartung, et al., 2009; Venbrux, et al., 2002).

Multiple Sclerosis or Chronic Cerebrospinal Venous Insufficiency: Venous angioplasty and stent placement have been proposed as a treatment for chronic cerebrospinal venous insufficiency (CCSVI), a controversial condition, largely disproven, characterized by assumed anomalies of cerebrospinal veins that interfere with venous drainage from the brain. It has been reported that invasive treatments for CCSVI are not beneficial, and there are reports of harm with such treatments. Evidence in the peer-reviewed literature states that endovascular venoplasty or stenting procedures to treat patients with multiple sclerosis for presumed CCSVI is not recommended (Jagannath, et al., 2019; Olek, 2019; Siddiqui, et al., 2014; Zamboni, et al., 2012; National Institute for Health and Clinical Excellence (NICE) (United Kingdom) 2012; Vedantham, et al., 2010).

U.S. Food and Drug Administration (FDA): A Food and Drug Administration (FDA) alert issued in May 2012 reported the potential for adverse events following endovascular interventions for Multiple Sclerosis. 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.

Venous Thoracic Outlet Syndrome (vTOS)

Thoracic outlet syndrome (TOS) refers to a constellation of signs and symptoms that arise from compression of the neurovascular bundle by various structures in the area just above the first rib and behind the clavicle, within the confined space of the thoracic outlet. Distinct terms are used to describe the predominantly affected structure, including neurogenic (nTOS) from brachial plexus compression, venous (vTOS) from subclavian vein compression, and arterial (aTOS) from subclavian artery compression. vTOS may be further divided into four distinct presentations: acute thrombosis; chronic stenosis (effort thrombosis); intermittent obstruction without thrombosis; and complete obstruction. vTOS accounts for 3% of cases of thoracic outlet syndrome. vTOS typically occurs in individuals who perform vigorous repetitive exertion of the upper extremities, usually with the arms above shoulder level. Forearm fatigue within minutes of using the arm may be present in vTOS. Upper extremity edema due to varying degrees of venous compression or overt deep vein thrombosis is the hallmark of vTOS. Upper extremity venous thrombosis due to thoracic outlet compression is termed "spontaneous" to distinguish it from instrumentation-related or "catheter-induced" venous thrombosis. Spontaneous upper extremity venous thrombosis is historically referred to as Paget-Schroetter syndrome (PSS) or "effort" thrombosis. Ultrasonography is the initial imaging test to evaluate vTOS. Contrast-enhanced computed tomography (CT) and magnetic resonance (MR) are used to establish the diagnosis of vTOS. Treatment for vTOS involves consideration of three therapies in addition to anticoagulation: thrombolysis, decompression, and venoplasty. Which therapy is selected depends on the clinical presentation of patients with vTOS. Treatment is indicated only for symptomatic patients. The mere presence of a cervical rib or other rib anomalies does not indicate a need to intervene (Goshima, et al., 2020; Jones, 2019; Hussain, et al., 2016).

Literature Review; Evidence in the peer-reviewed medical literature for the approach to vascular TOS is limited to case series, with a paucity of randomized controlled trials and prospective data (Hussain, et al., 2016; Povlsen, et al., 2014).

In a Cochrane systematic review, Povlsen et al. (2014) evaluated the beneficial and adverse effects of the available operative and non-operative interventions for the treatment of TOS a minimum of six months after the intervention. This review was complicated by a lack of generally accepted diagnostic criteria for the diagnosis of TOS. The authors reported that their findings suggest that further high quality prospective randomized controlled clinical trials are needed in this field, which is dominated by low quality, observer-biased observational studies. In particular, there was a lack of any randomized controlled trials for the treatment of vascular thoracic outlet syndrome. There is a need for randomized, double-blind trials that compare the effects of different interventions with each other, such as different types of surgeries, or surgeries versus more conservative treatments options, or commonly-used interventions versus no interventions.

In a single-center retrospective case series review, Bamford et al. (2012) evaluated the management and outcomes of vTOS. Initially, 35 cases were identified, of which all underwent first rib resection for subclavian venous thrombosis. Two individuals were excluded from the review due to loss of follow-up and incomplete

notes. Of the 33 cases reviewed, 20 individuals were treated for vTOS prior to 2006 (group A) and the remaining 13 were treated in 2006 and after (group B). Duplex ultrasound imaging was recorded on presentation in 31 of the 33 cases (94%) and of these, 3 cases had additional magnetic resonance angiography (MRA) of the affected limb. A total of 17 of the 33 cases (51.5%) were initially treated with catheter-directed thrombolysis (CDT) and six cases (35%) underwent balloon angioplasty before decompression of the thoracic outlet. The remaining 11 (65%) had recanalized sufficiently to proceed with thoracic outlet decompression with CDT alone. Most cases of CDT, 10/17 (58.8%) occurred in group B. In group A, most cases, 13/33 (39.3%) were treated initially with a variable period of anticoagulation. All individuals who subsequently underwent thoracic outlet decompression had evidence of venous recanalization before surgery. Postoperatively, 91% of individuals had patent veins at discharge from follow-up and were free of symptoms at a median of 44 months. Those treated within 7 days of symptom onset with CDT and excision of first rib in less than 30 days had improved symptom-free rates. The authors reported that the lack of power in this study made it difficult to reach firm conclusions regarding the effectiveness of the proposed protocol for vTOS management. Further noted was that while not conclusive, this study suggests that a treatment algorithm of early referral, immediate CDT and surgical decompression may lead to improved vTOS outcomes. The authors reported that multicenter, prospective trials over a longer period of time are needed in this field to fully evaluate the impact of this proposed management strategy. The quality of evidence available for the individual areas for management of vTOS is limited and, as such, standardization of treatment for vTOS is lacking.

Skalicka et al. (2011) performed a single center retrospective analysis of 73 patients treated for venous thrombotic complications secondary to vTOS to analyze long-term outcomes of different treatments stratified by symptom severity. Long-term follow-up with duplex ultrasound was completed 6-12 months after the initial clinical event. The initial treatment provided was based on severity of symptoms. Endovascular procedures were attempted in 41 cases (56%) as a primary thrombosis treatment. A total of 12 additional individuals were treated with an endovascular approach due to failure of conservative treatment based on low molecular weight heparin alone. Endovascular treatment by balloon angioplasty was performed in 35 individuals. In seven cases, re-treatment was necessary due to suboptimal patency or re-thrombosis. In 12 individuals, failure of the endovascular approach resulted in primary surgical intervention consisting of thrombectomy followed by decompression. An additional 22 individuals with persistent symptoms underwent subsequent surgical decompression. Conservative treatment consisting of IV or low molecular weight heparin was used for 32 cases (44%) with mild symptoms. Of these, 12 subsequently were referred for endovascular treatment and eight for elective surgery due to persistent symptoms. None of the cases required primary surgical thrombectomy or revascularization. Follow-up assessment of patency by ultrasound and clinical exam was performed in 62 (82%). Surgery was associated with a significantly lower rate of ultrasound-detected signs of persistent vascular compression as compared to treatment consisting only of endovascular and/or conservative therapy. However, the rate of persistent clinical symptoms was similar in both groups. Study data demonstrated that initial endovascular treatment provided as first-line therapy to highly symptomatic individuals and to those with failure of conservative treatment improved symptoms in 77%, avoiding the need for acute surgery. A total of 13 (23%) did have persistent clinical symptoms. Study limitations included a limited sample of cases from a single center. The authors concluded that long-term outcomes in those for whom surgery was required were satisfactory and comparable to those requiring only conservative and/or endoluminal treatment.

In a prospective study, Schneider et al. (2004) evaluated the safety and efficacy of combined thoracic outlet decompression with intraoperative percutaneous angioplasty (PTA) performed in one stage. Residual subclavian vein stenosis after operative thoracic outlet decompression is common in patients with venous thoracic outlet syndrome. Over 3 years 25 consecutive patients underwent treatment for venous thoracic outlet syndrome with a standard protocol at two institutions. Twenty-one patients (84%) underwent preoperative thrombolysis to treat axillosubclavian vein thrombosis. First-rib resection was performed through combined supraclavicular and infraclavicular incisions. Intraoperative venography and subclavian vein PTA were performed through a percutaneous basilic vein approach. Postoperative anticoagulation therapy was not used routinely. Venous duplex ultrasound scanning was performed postoperatively and at 1, 6, and 12 months. Intraoperative venography enabled identification of residual subclavian vein stenosis in 16 patients (64%), and all underwent intraoperative PTA with 100% technical success. Postoperative duplex scans documented subclavian vein patency in 23 patients (92%). Complications included subclavian vein recurrent thrombosis in two patients (8%), and both underwent percutaneous mechanical thrombectomy, with restoration of patency in one patient. One-year primary and secondary patency rates were 92% and 96%, respectively, at life-table analysis. The authors

state that subclavian vein stent placement is rarely indicated, and routine placement of subclavian vein stents in patients with venous thoracic outlet syndrome should be discouraged.

A 2020 UptoDate document on primary (spontaneous) upper extremity deep vein thrombosis states that primary "spontaneous" upper extremity deep vein thrombosis is rare and is defined as thrombosis of the deep veins draining the upper extremity due to anatomic abnormalities of the thoracic outlet causing axillosubclavian compression and subsequent thrombosis. The syndrome is appropriately termed venous thoracic outlet syndrome but is also referred to as Paget-Schroetter syndrome. A treatment approach that includes anticoagulation, catheter-directed thrombolysis, and thoracic outlet decompression is aimed at relieving acute symptoms and minimizing complications, including recurrent thromboembolism and post-thrombotic syndrome. The authors report that although there is uniform agreement that thoracic outlet decompression should be performed early in patients with acute axillosubclavian thrombosis, debate exists over the management of the vein. Concurrent with thoracic outlet decompression, some feel that venolysis or venoplasty (percutaneous transluminal or open) is sufficient while others advocate vein repair (patch venoplasty, interposition vein graft, vein bypass, jugular turn-down). There are insufficient data to support one approach over another. Sometimes percutaneous transluminal angioplasty (PTA) is needed to keep the vein open following thrombolysis until thoracic outlet decompression can be accomplished. It is recommended that stenting prior to thoracic outlet decompression be avoided. Shoulder movements subject the stent to repetitive compression that can lead to stent fracture. In one small observational study, stent use was found to be an independent risk factor for upper extremity rethrombosis. Once thoracic outlet decompression has been performed, stenting for residual or recurrent stenosis may be warranted with acceptable clinical outcomes (Goshima, 2020).

Professional Societies/Organizations: No professional society clinical guidelines or recommendations were found for venous thoracic outlet syndrome.

The Society for Vascular Surgery (SVS) published reporting standards for thoracic outlet syndrome (Illig, et al., 2016). Reporting standards for workup, treatment, and assessment of results are outlined, as are reporting standards for all phases of vTOS. Balloon venoplasty is mentioned as an adjunct measure that needs to be documented for treatment axillosubclavian venous thrombolysis. Stenting is contraindicated in this situation.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD	National	Percutaneous Transluminal Angioplasty (PTA)/(20.7)	1/1/2013
LCD	First Coast Service Options, Inc.	Endovenous Stenting/L37893	11/21/2019
LCD	Novitas Solutions, Inc.	Endovenous Stenting/L38231	12/30/2019
LCD	Wisconsin Physician Services	Non-Coronary Vascular Stents/L35998	8/7/2020
LCD	Novitas Solutions, Inc.	Non-Coronary Vascular Stents/L35084	10/17/2019
LCD	National Government Services	Venous Angioplasty with or without Stent Placement for the Treatment of Chronic Cerebrospinal Venous Insufficiency/L35028	11/14/2019

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
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	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein
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	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; each additional vein (List separately in addition to code for primary procedure)
37252	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel (List separately in addition to code for primary procedure)
37253	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (List separately in addition to code for primary procedure)

Considered Not Medically Necessary:

CPT® Codes	Description
61630	Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous
61635	Transcatheter placement of intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed

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