Medical Coverage Policy

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Venous Angioplasty With or Without Stent Placement in Adults

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Overview

This Coverage Policy addresses venous angioplasty with or without stent placement in adults ≥18 years of age. This policy does not address venous angioplasty with or without stent placement in individuals under 18 years of age. Percutaneous revascularization of the lower extremities in Adults is addressed in a separate Coverage Policy.

Coverage Policy

Venous angioplasty with or without stent placement in an adult ≥ 18 years of age is considered medically necessary for the following indications:

- thrombotic obstruction of major hepatic veins (e.g., Budd-Chiari Syndrome)
- iliac vein compression syndrome (e.g., May-Thurner Syndrome)
- superior vena cava syndrome
- pulmonary vein stenosis
- stenotic or thrombosed arterio-venous-dialysis access grafts

For all other indications venous angioplasty with or without stent placement is considered not medically necessary.
General Background

Angioplasty, with or without 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).

There are numerous conditions which have been treated with venous angioplasty with or without stenting, including, but not limited to, iliac vein compression syndrome (May-Thurner syndrome), 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, 2018; 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 iliocaval territory. MTS is also referred to as iliocaval 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 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, 2019; Kaltenmeier, et al., 2017).

Literature Review: Moudgill et al (2009) reported in a review that current management of May-Thurner syndrome largely involves endovascular therapy. A review was conducted of six studies containing at least five patients with May-Thurner syndrome 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 May-Thurner syndrome. Review of the current literature supports treatment via catheter-directed thrombolysis followed by stent placement with good early results.

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=0.021). 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.

Use Outside of the US: Cardiovascular and Interventional Radiological Society of Europe (CIRSE): CIRSE standards of practice guidelines on iliocaval stenting conclude that stenting in chronic iliocaval 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).

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. 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, 2019; 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 reintervention, 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<.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.”

**Other Indications**
Venous angioplasty with or without stent placement has been proposed for use in a number of indications including, but not limited to, idiopathic intracranial hypertension (IIH), iliac vein stenosis, left iliac vein compression associated with pelvic congestion syndrome, Multiple Sclerosis or chronic cerebrospinal venous insufficiency, venous thoracic outlet syndrome (vTOS). Most of the evidence in the peer-reviewed literature for 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 most common symptoms are headache, visual disturbance and tinnitus. Papilledema is present in at least 95%. Medical treatment generally consists of a combination of carbonic anhydrase inhibitors such as topiramate or acetazolamide, to decrease CSF production, and symptomatic treatment for headache. For medically refractory patients, surgical strategies that have most commonly been used include CSF diversion with ventriculoperitoneal or lumboperitoneal shunts (VPS or LPS) and optic nerve sheath fenestration (ONSF). The underlying pathophysiology of IIH has yet to be fully defined, but 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 stenting of the stenotic dural venous sinus may represent a therapeutic option for medically refractory IIH (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 retrospective reviews and case series. Further studies are necessary to determine the long-term outcomes and the optimal management of medically refractory IIH (Shazly, et al., 2018; Saber, et al., 2018; Matloob, et al., 2017; Piper, et al., 2015; Starke, et al., 2015; Lai, et al., 2014).

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 stenting (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.

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.
Iliac Vein Stenosis: Evidence in the peer-reviewed literature addresses venous stenting of the iliac veins in the context of an ilio-femoral obstruction or thrombosis or for the treatment of iliac vein compression syndrome and May-Thurner Syndrome. There is insufficient evidence in the published peer-reviewed literature regarding the long-term outcomes or safety and efficacy of venous stenting to relieve peripheral edema or for the treatment of iliac vein stenosis without chronic iliac vein occlusions/obstructions or ilio-femoral thrombosis (Alguire, 2018; Jones, et al., 2017).

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; Kim, et al., 2018; 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 (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 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., 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 (35%) underwent first rib excision and were then treated with CDT alone. In group B, 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.

Professional Societies/Organizations: Society for Vascular Surgery (SVS): The 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.

Centers for Medicare & Medicaid Services (CMS)
- National Coverage Determinations (NCDs): No NCD found.
- Local Coverage Determinations (LCDs): Multiple LCDs found. Refer to the LCD table of contents link in the reference section.

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:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>37238</td>
<td>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</td>
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</tbody>
</table>
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)


References


