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Clinical UM Guideline

Subject:	**Venous Angioplasty with or without Stent Placement or Venous Stenting Alone**		
Guideline #:	**CG-SURG-106.00122**	**Publish Date:**	**02/05/2020**
Status:	**New**	**Last Review Date:**	**11/07/2019**

Description

This document addresses venous angioplasty with or without stent placement, or venous stenting alone, as a treatment modality for a variety of conditions, including, but not limited to: venous thoracic outlet syndrome, superior vena cava syndrome, Budd-Chiari syndrome, congenital cardiac defects, lower extremity venous congestion, and as a method to improve venous flow in individuals with multiple sclerosis and chronic cerebrospinal venous insufficiency (CCSVI).

Note: Angiographic evaluation and endovascular intervention for dialysis access circuit dysfunction is not addressed in this document. For more information, please refer to:

- **CG-SURG-93 Angiographic Evaluation and Endovascular Intervention for Dialysis Access Circuit Dysfunction**

Clinical Indications

Medically Necessary:

Venous angioplasty with or without stent placement or venous stenting alone is considered medically necessary for treatment of the following conditions:

A. **Venous thoracic outlet syndrome; or**
B. **Thrombotic obstruction of major hepatic veins (Budd-Chiari syndrome); or**

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C. **Superior vena cava syndrome; or**
D. **Iliac vein compression syndrome (for example, May-Thurner Syndrome); or**
E. **Pulmonary vein stenosis; or**
F. **Congenital heart disease including, but not limited to:**
   1. **Stenosis or hypoplasia of a pulmonary artery in a child; or**
   2. **Symptomatic stenosis/occlusion of superior or inferior vena cava; or**
   3. **Venous narrowing due to repair of sinus venosus atrial septal defect (ASD); or**
   4. **Venous obstruction of an atrial baffle following Mustard or Senning repair of transposition of the great arteries.**

~~Investigational and~~ Not Medically Necessary:

Venous angioplasty with or without stent placement or venous stenting alone is considered ~~investigational and~~ not medically necessary for the treatment of all other conditions not listed above including, but not limited to:

A. Multiple sclerosis; or
B. Chronically occluded iliac veins; or
C. Idiopathic intracranial hypertension (pseudotumour cerebri); or
D. Ilio-femoral venous thrombosis; or
E. Nutcracker syndrome.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

~~**When services are Medically Necessary:**~~

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CPT	
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**
ICD-10 Procedure	
027Q04Z-027Q4ZZ	**Dilation of right pulmonary artery [by approach and with or without device; includes codes 027Q04Z, 027Q0DZ, 027Q0ZZ, 027Q34Z, 027Q3DZ, 027Q3ZZ, 027Q44Z, 027Q4DZ, 027Q4ZZ]**
027R04Z-027R4ZZ	**Dilation of left pulmonary artery [by approach and with or without device; includes codes 027R04Z, 027R0DZ, 027R0ZZ, 027R34Z, 027R3DZ, 027R3ZZ, 027R44Z, 027R4DZ, 027R4ZZ]**
027S04Z-027S4ZZ	**Dilation of right pulmonary vein [by approach and with or without device; includes codes 027S04Z, 027S0DZ, 027S0ZZ, 027S34Z, 027S3DZ, 027S3ZZ, 027S44Z, 027S4DZ, 027S4ZZ]**
027T04Z-027T4ZZ	**Dilation of left pulmonary vein [by approach and with or without device; includes codes 027T04Z , 027T0DZ, 027T0ZZ, 027T34Z, 027T3DZ, 027T3ZZ, 027T44Z, 027T4DZ, 027T4ZZ]**
027V04Z-027V4ZZ	**Dilation of superior vena cava [by approach and with or without device; includes codes 027V04Z, 027V0DZ, 027V0ZZ, 027V34Z, 027V3DZ, 027V3ZZ, 027V44Z, 027V4DZ, 027V4ZZ]**

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05700DZ-05704ZZ	**Dilation of azygos vein [by approach and with or without device; includes codes 05700DZ, 05700ZZ, 05703DZ, 05703ZZ, 05704DZ, 05704ZZ]**
05710DZ-05714ZZ	**Dilation of hemiazygos vein [by approach and with or without device, includes codes 05710DZ, 05710ZZ, 05713DZ, 05713ZZ, 05714DZ, 05714ZZ]**
05730D1-05744ZZ	**Dilation of innominate vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 05730D1, 05730DZ, 05730Z1, 05730ZZ, 05733D1, 05733DZ, 05733Z1, 05733ZZ, 05734D1, 05734DZ, 05734Z1, 05734ZZ, 05740D1, 05740DZ, 05740Z1, 05740ZZ, 05743D1, 05743DZ, 05743Z1, 05743ZZ, 05744D1, 05744DZ, 05744Z1, 05744ZZ] Note: codes ending in 1 effective 10/01/18.**
05750D1-05764ZZ	**Dilation of subclavian vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 05750D1, 05750DZ, 05750Z1, 05750ZZ, 05753D1, 05753DZ, 05753Z1, 05753ZZ, 05754D1, 05754DZ, 05754Z1, 05754ZZ, 05760D1, 05760DZ, 05760Z1, 05760ZZ, 05763D1, 05763DZ, 05763Z1, 05763ZZ, 05764D1, 05764DZ, 05764Z1, 05764ZZ] Note: codes ending in 1 effective 10/01/18.**
05770D1-05784ZZ	**Dilation of axillary vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 05770D1, 05770DZ, 05770Z1, 05770ZZ, 05773D1, 05773DZ, 05773Z1, 05773ZZ, 05774D1, 05774DZ, 05774Z1, 05774ZZ, 05780D1, 05780DZ, 05780Z1, 05780ZZ, 05783D1, 05783DZ, 05783Z1, 05783ZZ, 05784D1, 05784DZ, 05784Z1, 05784ZZ] Note: codes ending in 1 effective 10/01/18.**
05790D1-057A4ZZ	**Dilation of brachial vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 05790D1, 05790DZ, 05790Z1, 05790ZZ, 05793D1, 05793DZ, 05793Z1, 05793ZZ, 05794D1, 05794DZ, 05794Z1, 05794ZZ, 057A0D1, 057A0DZ, 057A0Z1, 057A0ZZ, 057A3D1, 057A3DZ, 057A3Z1, 057A3ZZ, 057A4D1, 057A4DZ, 057A4Z1, 057A4ZZ] Note: codes ending in 1 effective 10/01/18.**
057B0D1-057C4ZZ	**Dilation of basilic vein [right or left, by approach and with or without device or drug-coated balloon, includes 057B0D1, 057B0DZ, 057B0Z1, 057B0ZZ, 057B3D1, 057B3DZ, 057B3Z1, 057B3ZZ, 057B4D1, 057B4DZ, 057B4Z1, 057B4ZZ, 057C0D1, 057C0DZ, 057C0Z1, 057C0ZZ, 057C3D1, 057C3DZ, 057C3Z1,**

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	057C3ZZ, 057C4D1, 057C4DZ, 057C4Z1, 057C4ZZ] Note: codes ending in 1 effective 10/01/18.
057D0D1-057F4ZZ	**Dilation of cephalic vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 057D0D1, 057D0DZ, 057D0Z1, 057D0ZZ, 057D3D1, 057D3DZ, 057D3Z1, 057D3ZZ, 057D4D1, 057D4DZ, 057D4Z1, 057D4ZZ, 057F0D1, 057F0DZ, 057F0Z1, 057F0ZZ, 057F3D1, 057F3DZ, 057F3Z1, 057F3ZZ, 057F4D1, 057F4DZ, 057F4Z1, 057F4ZZ] Note: codes ending in 1 effective 10/01/18.**
057G0DZ-057H4ZZ	**Dilation of hand vein [right or left, by approach and with or without device, includes codes 057G0DZ, 057G0ZZ, 057G3DZ, 057G3ZZ, 057G4DZ, 057G4ZZ, 057H0DZ, 057H0ZZ, 057H3DZ, 057H3ZZ, 057H4DZ, 057H4ZZ]**
057L0DZ-057L4ZZ	**Dilation of intracranial vein [by approach & with or without device, includes codes 057L0DZ, 057L0ZZ, 057L3DZ, 057L3ZZ, 057L4DZ, 057L4ZZ]**
057M0DZ-057N4ZZ	**Dilation of internal jugular vein [right or left, by approach and with or without device; includes codes 057M0DZ, 057M0ZZ, 057M3DZ, 057M3ZZ, 057M4DZ, 057M4ZZ, 057N0DZ, 057N0ZZ, 057N3DZ, 057N3ZZ, 057N4DZ, 057N4ZZ]**
057P0DZ-057Q4ZZ	**Dilation of external jugular vein [right or left, by approach and with or without device; includes codes 057P0DZ, 057P0ZZ, 057P3DZ, 057P3ZZ, 057P4DZ, 057P4ZZ, 057Q0DZ, 057Q0ZZ, 057Q3DZ, 057Q3ZZ, 057Q4DZ, 057Q4ZZ]**
057R0DZ-057S4ZZ	**Dilation of vertebral vein [right or left, by approach and with or without device; includes codes 057R0DZ, 057R0ZZ, 057R3DZ, 057R3ZZ, 057R4DZ, 057R4ZZ, 057S0DZ, 057S0ZZ, 057S3DZ, 057S3ZZ, 057S4DZ, 057S4ZZ]**
057T0DZ-057V4ZZ	**Dilation of face vein [right or left, by approach and with or without device; includes codes 057T0DZ, 057T0ZZ, 057T3DZ, 057T3ZZ, 057T4DZ, 057T4ZZ, 057V0DZ, 057V0ZZ, 057V3DZ, 057V3ZZ, 057V4DZ, 057V4ZZ]**
057Y0DZ-057Y4ZZ	**Dilation of upper vein [by approach and with or without device; includes codes 057Y0DZ, 057Y0ZZ, 057Y3DZ, 057Y3ZZ, 057Y4DZ, 057Y4ZZ]**
06700DZ-06704ZZ	**Dilation of inferior vena cava [by approach and with or without device; includes codes 06700DZ, 06700ZZ, 06703DZ, 06703ZZ, 06704DZ, 06704ZZ]**

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06710DZ-06714ZZ	**Dilation of splenic vein [by approach and with or without device; includes codes 06710DZ, 06710ZZ, 06713DZ, 06713ZZ, 06714DZ, 06714ZZ]**
06720DZ-06724ZZ	**Dilation of gastric vein [by approach and with or without device; includes codes 06720DZ, 06720ZZ, 06723DZ, 06723ZZ, 06724DZ, 06724ZZ]**
06730DZ-06734ZZ	**Dilation of esophageal vein [by approach and with or without device; includes codes 06730DZ, 06730ZZ, 06733DZ, 06733ZZ, 06734DZ, 06734ZZ]**
06740DZ-06744ZZ	**Dilation of hepatic vein [by approach and with or without device; includes codes 06740DZ, 06740ZZ, 06743DZ, 06743ZZ, 06744DZ, 06744ZZ]**
06750DZ-06754ZZ	**Dilation of superior mesenteric vein [by approach and with or without device; includes codes 06750DZ, 06750ZZ, 06753DZ, 06753ZZ, 06754DZ, 06754ZZ]**
06760DZ-06764ZZ	**Dilation of inferior mesenteric vein [by approach and with or without device; includes codes 06760DZ, 06760ZZ, 06763DZ, 06763ZZ, 06764DZ, 06764ZZ]**
06770DZ-06774ZZ	**Dilation of colic vein [by approach and with or without device; includes codes 06770DZ, 06770ZZ, 06773DZ, 06773ZZ, 06774DZ, 06774ZZ]**
06780DZ-06784ZZ	**Dilation of portal vein [by approach and with or without device; includes codes 06780DZ, 06780ZZ, 06783DZ, 06783ZZ, 06784DZ, 06784ZZ]**
06790DZ-067B4ZZ	**Dilation of renal vein [right or left, by approach and with or without device; includes codes 06790DZ, 06790ZZ, 06793DZ, 06793ZZ, 06794DZ, 06794ZZ, 067B0DZ, 067B0ZZ, 067B3DZ, 067B3ZZ, 067B4DZ, 067B4ZZ]**
067C0DZ-067D4ZZ	**Dilation of common iliac vein [right or left, by approach and with or without device; includes codes 067C0DZ, 067C0ZZ, 067C3DZ, 067C3ZZ, 067C4DZ, 067C4ZZ, 067D0DZ, 067D0ZZ, 067D3DZ, 067D3ZZ, 067D4DZ, 067D4ZZ]**
067F0DZ-067G4ZZ	**Dilation of external iliac vein [right or left, by approach and with or without device; includes codes 067F0DZ, 067F0ZZ, 067F3DZ, 067F3ZZ, 067F4DZ, 067F4ZZ, 067G0DZ, 067G0ZZ, 067G3DZ, 067G3ZZ, 067G4DZ, 067G4ZZ]**
067H0DZ-067J4ZZ	**Dilation of hypogastric vein [right or left, by approach and with or without device; includes codes 067H0DZ, 067H0ZZ, 067H3DZ, 067H3ZZ, ,067H4DZ, 067H4ZZ, 067J0DZ, 067J0ZZ, 067J3DZ, ,067J3ZZ, 067J4DZ, 067J4ZZ]**

067M0DZ-067N4ZZ	**Dilation of femoral vein [right or left, by approach and with or without device; includes codes 067M0DZ, 067M0ZZ, 067M3DZ, 067M3ZZ, 067M4DZ, 067M4ZZ, 067N0DZ, 067N0ZZ, 067N3DZ, 067N3ZZ, 067N4DZ, 067N4ZZ]**
067P0DZ-067Q4ZZ	**Dilation of saphenous vein [right or left, by approach and with or without device; includes codes 067P0DZ, 067P0ZZ, 067P3DZ, 067P3ZZ, 067P4DZ, 067P4ZZ, 067Q0DZ, 067Q0ZZ, 067Q3DZ, 067Q3ZZ, 067Q4DZ, 067Q4ZZ]**
067T0DZ-067V4ZZ	**Dilation of foot vein [right or left, by approach and with or without device; includes codes 067T0DZ, 067T0ZZ, 067T3DZ, 067T3ZZ, 067T4DZ, 067T4ZZ, 067V0DZ, 067V0ZZ, 067V3DZ, 067V3ZZ, 067V4DZ, 067V4ZZ]**
067Y0DZ-067Y4ZZ	**Dilation of lower vein [by approach and with or without device; includes codes 067Y0DZ, 067Y0ZZ, 067Y3DZ, 067Y3ZZ, 067Y4DZ, 067Y4ZZ]**

ICD-10 Diagnosis	
C38.1-C38.3	**Malignant neoplasm of mediastinum**
C38.8	**Malignant neoplasm of overlapping sites of heart, mediastinum and pleura**
G54.0	**Brachial plexus disorders**
I26.01-I26.99	**Pulmonary embolism**
I28.8	**Other diseases of pulmonary vessels [specified as pulmonary vein stenosis]**
I82.0	**Budd-Chiari syndrome**
I82.210-I82.211	**Embolism and thrombosis of superior vena cava**
I82.220-I82.221	**Embolism and thrombosis of inferior vena cava**
I87.1	**Compression of vein [specified as superior vena cava syndrome or iliac vein compression]**
Q20.0-Q20.9	**Congenital malformations of cardiac chambers and connections**
Q21.0-Q21.9	**Congenital malformations of cardiac septa**
Q25.0-Q25.9	**Congenital malformations of great arteries**
Q26.0-Q26.9	**Congenital malformations of great veins**
R10.84	**Generalized abdominal pain**
R16.0	**Hepatomegaly, not elsewhere classified**
R18.8	**Other ascites**

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~~**When services are Investigational and Not Medically Necessary:**~~
~~**For the procedure codes listed above for all other diagnoses, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.**~~

Intracranial venous sinus
~~**When services are also Investigational and Not Medically Necessary for venous sinus stenting or angioplasty:**~~
Note: the following services are considered not medically necessary for the diagnosis listed:

CPT	
61630	**Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous**
61635	**Transcatheter placement of an intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed**
ICD-10 Procedure	
057L0DZ-057L4ZZ	**Dilation of intracranial vein [by approach and with or without device; includes codes 057L0DZ, 057L0ZZ, 057L3DZ, 057L3ZZ, 057L4DZ, 057L4ZZ]**
ICD-10 Diagnosis	
G93.2	**Benign intracranial hypertension**

Discussion/General Information

Venous angioplasty is a procedure which can be performed during a venogram to open or bypass veins. It also can be used for placement of a stent, which keeps the vessel in an open position to allow for improved blood flow.

There are numerous conditions which have been successfully treated with venous angioplasty, including Budd-Chiari syndrome, superior vena cava syndrome, iliac vein compression syndrome (for example, May-Thurner syndrome), and congenital heart disease. Venous angioplasty has been studied to treat a variety of

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other conditions, including but not limited to the treatment of MS or CCSVI, chronically occluded iliac veins, iliofemoral venous thrombosis, idiopathic intracranial hypertension and nutcracker syndrome; however, use is not in accordance with generally accepted standards of medical practice.

Venous Thoracic Outlet Syndrome (vTOS)

vTOS is caused by compression of peripheral nerves and vascular structures along their course through the upper thoracic aperture to the axilla (Skalicka, 2011). The evidence regarding venous angioplasty for vTOS consists mainly of retrospective analyses (Bamford, 2012; Skalicka, 2011).

Skalicka and colleagues (2011) performed a retrospective analysis of 73 individuals treated at a single institution between 2001 and 2007 for venous thrombotic complications secondary to vTOS. 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 7 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 8 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.

Bamford and colleagues (2012), in a single-center retrospective review, evaluated the management and outcomes of vTOS from 2002 through 2009. 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 6 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.

Thrombotic Obstruction of Major Hepatic Veins (Budd-Chiari Syndrome)

Data to support angioplasty with or without stent placement for the treatment of Budd-Chiari syndrome consists of multiple retrospective studies or case series of varying size (Fisher, 1999; Han, 2013; Meng, 2011; Pelage, 2003; Qiao, 2005; Zhang, 2003).

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In the largest case series, Meng and colleagues (2011) evaluated endovascular treatment of Budd-Chiari syndrome (BCS) in 903 cases at a single Chinese center. The obstruction in the inferior vena cava (IVC) was carried out first, then obliteration or stenosis in the IVC was opened or dilated and a stent was placed. The procedure was reported to be successful in 821 out of 903 cases. Complications included acute renal failure (8 cases), hepatic coma (2 cases), and acute heart failure (43 cases). The authors concluded that endovascular treatment has become the treatment of choice for BCS because of its minimal trauma and fast recovery.

More recently, Han and colleagues (2013) evaluated the long-term outcomes of percutaneous recanalization and predictors of patency and survival in a retrospective case series of individuals with BCS at a single Chinese center. Between July 1999 and August 2010, 177 consecutive cases of primary BCS were treated with percutaneous recanalization and followed up until their last clinical evaluation or death. Percutaneous recanalization was reported as technically successful in 168 of the 177 cases (95%). A total of 51 of the 168 individuals (30%) were treated with percutaneous transluminal angioplasty (PTA) alone and 117 (70%) were treated with a combination of PTA and stent placement. Procedure-related complications occurred in 7 of the 168 individuals (4%). The cumulative 1-, 5- and 10-year primary patency rates were 95%, 77% and 58%, respectively. Independent predictors of reocclusion included increased white blood cell count and use of PTA alone. The cumulative 1-, 5- and 10-year secondary patency rates were 97%, 90% and 86%, respectively. There were 22 deaths during a median follow-up of 30 months (range, 0.25-137 months). The cumulative 1-, 5- and 10-year survival rates were 96%, 83% and 73%, respectively. Independent predictors of survival included variceal bleeding, increased alkaline phosphatase and blood urea nitrogen levels, and reocclusion.

Stenosis or Occlusion associated with Superior Vena Cava Syndrome

Superior vena cava stenting for the treatment of malignant and nonmalignant superior vena cava obstruction is well established (Schindler, 1999; Uberoi, 2006). Venous angioplasty is often necessary prior to stenting to offer safe palliation of potentially fatal complications associated with mediastinal malignant disease and compares very favorably with standard therapies such as chemotherapy and radiotherapy. Superior vena cava syndrome can also be caused by benign occlusion from chronic indwelling catheters

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resulting in arm or facial swelling, difficulty breathing, or an inability to obtain vital venous access, among others.

Iliac Vein Compression Syndrome (for example, May-Thurner Syndrome)

Some common causes of iliac vein compression syndrome (IVCS) are trauma, iatrogenic injury, congenital hypoplasia/aplasia of the IVC, and hypercoagulability, but the most common cause is malignant, juxtahepatic invasion or extraluminal compression of the IVC (Kuetting, 2018). Diagnosis of iliac vein compression syndrome is based on the individual's clinical history and diagnostic imaging such as Doppler ultrasound, computed tomography venography (CTV), magnetic resonance venography, venography, and digital subtraction venography (DSV) (Liu, 2018).

In 2014, Liu and colleagues published a prospective cohort study with the aim to assess the prevalence of IVCS in individuals with chronic venous disease (CVD) of the left lower extremity, evaluate the sensitivity and specificity of CTV in the diagnosis of IVCS, and determine clinical utility of endovascular treatment of IVCS. The authors evaluated 324 individuals with CVD of the left lower extremity for IVCS. Diagnosis of IVCS was established through clinical history, duplex ultrasonography, ascending venography, and CTV with a prevalence of 14.8% (48/324). For individuals with an IVCS diagnosis, "the visualization of a > 50% reduction in the luminal diameter of the vein, the formation of collateral circulation, and a pressure gradient of > 2 mm Hg across the stenosis while the patient was in a supine position" was used to confirm it (Liu, 2014). IVCS-diagnosed individuals were included in the study and placed into one of two groups: thrombotic IVCS (n=12) or nonthrombotic IVCS (n=36). Results after endovascular treatment showed a technical success rate of 95.8%, a 1 year primary patency rate of 93% with no significant difference between the two groups (p=0.156), and few minor complications. Other 1-year outcomes included significant declines in median pain levels for both groups (p<0.05), edema relief rates of 81.8% and 58.5% in the thrombotic and nonthrombotic groups, respectively, and a rate of 71.4% for cumulative recurrence-free ulcer healing. In regards to CTV in the diagnosis of IVCS, the authors found it had the highest sensitivity and specificity compared to other imaging modalities used in the study; however, the values were not reported. Study limitations include small sample size and nonrandomized design. Larger randomized controlled trials are needed to confirm these findings.

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Venous duplex ultrasound (VDUS) imaging was evaluated as an imaging modality in diagnosing iliac vein stenosis after standard treatment of active chronic venous ulcers in 2016 by Mousa and colleagues. This was completed through a systematic retrospective review of a consecutive series of 36 individuals with 54 chronic venous ulcers on 38 limbs. Iliac vein stenosis was defined as > 50% stenosis. The authors found that chronic venous ulcers associated with a reflux duration > 2.5 seconds as measured by VDUS had significantly more iliac vein stenosis than those with a reflux duration < 2.5 seconds (p<0.001). Individuals with stent placement had significantly less recurrence of chronic venous ulcers (p=0.031). This study had positive findings; however, there were limitations to the study, including small sample size and retrospective design.

Liu and colleagues (2018) reported on an observational study that evaluated CTV in the diagnosis and severity assessment of IVCS. Blinded radiologists reviewed the imaging data of a group of individuals with CVD of the lower extremity (n=120) and a control group of individuals without CVD (n=68). Imaging data consisted of CTV, color ultrasonography, and conventional venography. The authors defined IVCS as "iliac vein compression > 50% in CVD patients" (Liu, 2018). Results showed that CTV required less procedure time when compared to conventional venography or color ultrasonography (p<0.001). In individuals with IVCS and venous ulcer [Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification: C5, healed venous ulcer; C6, active venous ulcer], ulcer healing time was significantly shorter in individuals with stent placement than those without stent placement (p<0.001). The authors concluded that CTV is safe and accurate in the diagnosis and severity assessment of IVCS, and iliac stent placement in CEAP 5 or 6 decreases healing time for venous ulcers caused by IVCS. Study limitations include data being collected at a single center, which may impact selection bias, small sample size, and retrospective design.

In 2018, Kuetting and colleagues published a retrospective analysis that evaluated technical and clinical outcomes of endovascular therapy as a treatment for symptomatic, malignant IVCS. From May 2000 to December 2015, 19 subjects were treated with stenting for malignant IVC obstruction. The treatment resulted in 100% technical success and 79% clinical success, which was measured by symptom improvement either temporally or indefinitely. The evaluators concluded that endovascular therapy is safe and effective for symptomatic, malignant IVCS; however, there are study limitations, including lack of statistical analysis, small sample size, and retrospective study design.

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Another type of IVCS is May-Thurner Syndrome. Endovascular therapy, specifically catheter-directed thrombolysis followed by stent placement, is the current primary intervention for May-Thurner syndrome (Moudgill, 2009). Review of the current literature, primarily case studies, case series, and retrospective studies indicates that angioplasty has also been used with mixed results.

Peters and colleagues (2012) report 3 cases and Zander (2008) reports 1 case of successful intervention in May-Thurner compression with angioplasty. However, Patel (2000) reports that 10 women with symptomatic May-Thurner syndrome failed an initial course of angioplasty and subsequently progressed to urokinase and stenting.

One retrospective case review from a surgical registry included 15 May-Thurner cases in which venous angioplasty with stenting restored and maintained venous flow through the compressed area. Titus and colleagues (2011) described a series of iliofemoral venous angioplasty and stenting occurring over a 4-year period. Charts were retrospectively reviewed for individual demographics, the extent of venous system involvement, the time course of the venous pathology, and any underlying cause. The 15 (42%) individuals with a recognized underlying etiology had been diagnosed with May-Thurner syndrome. An etiology was not recognized in 9 cases. A total of 36 subjects (40 limbs) were stented from January 2005 through December 2008. Both lower extremities were involved in 4 subjects. Thrombolysis was performed in 19 cases (52.8%). The mean follow-up time period in the study population was 10.5 months. One stent in the study occluded acutely and required restenting. Primary patency rates at 6, 12 and 24 months were 88%, 78.3% and 78.3%, respectively. Secondary patency rates for the same time frames were 100%, 95% and 95%. Better outcomes were seen in stenting for May-Thurner syndrome and idiopathic causes, whereas external compression and thrombophilia seemed to portend less favorable outcomes (p<0.001). Symptomatic improvement was reported in 24 of 29 individuals (83%) contacted by telephone follow-up.

In 2013, Hager and colleagues reported on a retrospective review of outcomes of endovascular intervention in May-Thurner syndrome individuals at two institutions. Based on presentation, individuals (n=70) were divided into either the postthrombotic group (group 1; 56 extremities) or the de novo presentation of chronic swelling/pain or ulceration but no DVT group (group 2; 21 extremities). Endovascular intervention was

performed on all individuals in both groups due to a > 50% diameter stenosis by IVUS or venogram. Mean follow up was 29.7 months in group 1 and 22.4 months in group 2. The authors found that "the overall primary patency of group 1 at 36 months by life-table analysis was 91% with a secondary patency of 95%, [and] the primary and secondary patency for group 2 was 91% at 36 months" (Hager, 2013). The retrospective design limits the study through possible reporting and selection bias, and missing data due to individuals lost to follow-up.

Pulmonary Vein Stenosis

Expert specialty consensus review indicates that venous angioplasty may be used for the treatment of pulmonary vein stenosis. Recently there have been published reports of venous angioplasty being successfully used to treat pulmonary vein stenosis following lung transplant (Loyalka, 2012).

Congenital Heart Disease

Angioplasty has long played a role in the treatment of numerous congenital cardiac defects including stenosis or hypoplasia of a pulmonary artery; coarctation of the aorta, transposition of the great arteries, repair of sinus venosus atrial septal defect (ASD); or venous obstruction following Mustard or Senning repair of transposition of the great arteries (Allen, 1998).

Treatment of Multiple Sclerosis: Chronic Cerebrospinal Venous Insufficiency and Dysautonomia

Various reports in the peer reviewed published literature (Zamboni 2009a; Zamboni, 2009b) describe a potential relationship between the abnormal venous circulation termed chronic cerebrospinal venous insufficiency (CCSVI) and multiple sclerosis (MS).

The role of venous angioplasty as a potential treatment option for those with MS and CCSVI has been evaluated. Zamboni and colleagues (2009c) evaluated the influence of venous angioplasty on the clinical outcome of CCSVI and MS. The authors characterized CCSVI as multiple stenoses of the principal pathways of extracranial venous drainage, including the internal jugular veins (IJV) and the azygous (AZY)

vein with development of insufficient drainage evidenced by cerebral magnetic resonance (MR) perfusion studies. In this study, a total of 65 consecutive participants with CCSVI and MS (35 with relapsing remitting MS [RRMS], 20 with secondary progressive MS [SPMS], and 10 with primary progressive MS [PPMS]), underwent venous angioplasty. Mean follow-up time was 18 months. Reported study results included lower postoperative venous pressure in the IJVs and AZY, a higher risk of restenosis in the IJVs compared with the AZY, improved MS clinical outcomes, and improved mental quality of life outcomes in all types of MS, except SPMS.

Doepp and colleagues (2010) evaluated CCSVI by performing extended extracranial and transcranial color coded sonography studies on 56 participants with MS and 20 controls. Study results demonstrated that blood flow direction in the internal jugular veins (IJVs) and vertebral veins was normal (in all but 1 person) and IJV stenosis was not present in any participants. The authors concluded that the results of their study did not suggest restricted venous drainage in participants with MS and challenged the hypothesis that CCSVI plays a role in the pathogenesis of MS.

Sundstrom and colleagues (2010) tested the hypothesis of CCSVI on 21 individuals with RRMS and 20 controls. All study participants were examined with magnetic resonance imaging (MRI) and those with RRMS also received contrast enhanced MRA. Findings reported to be associated with the MS hypothesis of CCSVI were not able to be reproduced. The authors concluded they found no support for a treatment rationale of endovascular procedures like angioplasty or stenting for the treatment of individuals with CCSVI and MS.

In a larger, controlled and blinded study, Zivadinov and colleagues (2011) performed transcranial and extracranial Doppler imaging on 499 people to determine the prevalence of CCSVI. The participants included 289 people with MS, 163 healthy controls (HC), 26 with other neurological diseases (OND), and 21 with clinically isolated syndrome (CIS) (having a first neurological episode that can often lead to definite MS). Researchers found an increased prevalence of CCSVI in MS, although lower than in earlier reports. In addition, CCSVI was found in non-MS participants. Variable rates were reported depending on whether or not borderline cases were included. When borderline cases were considered not to have CCSVI, the prevalence was 56.1% in MS, 42.3% in OND, 38.1% in CIS and 22.7% in HC. When borderline cases were

excluded from calculations, the prevalence of CCSVI was 62.5% in MS, 45.8% in OND, 42.1% in CIS and 25.5% in HC. The researchers reported modest sensitivity and specificity and stated that their findings point against CCSVI as having a primary causative role in MS.

Kostecki and colleagues (2011) prospectively evaluated 6-month follow-up results of endovascular treatment of CCSVI and MS. A total of 36 participants with confirmed MS and CCSVI underwent endovascular treatment by means of a uni- or bilateral jugular vein angioplasty with optional stent placement. Their MS-related disability status and quality of life were evaluated at 1, 3 and 6 months postoperatively by the following scales: Expanded Disability Status Scale (EDSS), Multiple Sclerosis Impact Scale (MSIS-29), Epworth Sleepiness Scale (ESS), Heat Intolerance scale (HIS) and Fatigue Severity Scale (FSS). For patency and restenosis rate assessment, the control ultrasound (US) duplex Doppler examination was used. After the procedure at 6 months, restenosis in post-PTA jugular veins was found in 33% of cases. Among 17 individuals who underwent stent implantation into the jugular vein, restenosis or partial in-stent thrombosis was identified in 55% of the cases. At the 6 month follow-up, there was no significant improvement in the EDSS or the ESS. The endovascular treatment of the CCSVI improved the quality of life according to the MSIS-29 scale but only up to 3 months after the procedure (with no differences in the 6 month follow-up assessment). After the jugular vein angioplasty (with or without stent placement) at 6 months, a statistically significant improvement was observed only in the FSS and the HIS. Based on their findings, the researchers concluded that "endovascular treatment in individuals with MS and concomitant CCSVI did not have an influence on the patient's neurological condition; however, in the mid-term follow-up, an improvement concerning some parameters influencing the patient's quality-of-life parameters was observed." They also emphasized that there is the need for a well-designed randomized controlled trial.

Zamboni and colleagues (2012) reported on a small series of 8 individuals with ultrasound criteria for CCSVI undergoing immediate venoplasty compared to 7 individuals undergoing delayed venoplasty. There were improvements on the EDSS (expanded disability status scale) for both groups following treatment, but no difference between groups in the first 6 months comparing immediate- versus delayed-treatment subjects. The relapse rate during the initial 6 months was 0.12% in the treatment group versus 0.66% in the control group; however, this difference did not meet statistical significance. There were also trends toward improvement for the immediate-treatment group on MRI scans, such as the number of T2 lesions, but these

differences also did not reach statistical significance. No short-term adverse events were reported following the procedure, but the rate of restenosis at 1 year was 27% in treated individuals.

Van Zuuren and colleagues (2012), in a Cochrane Review, concluded there was no high level evidence to either support or refute the efficacy and safety of angioplasty for CCSVI in people with MS. The authors further noted that additional robust and well-designed studies are needed.

In 2014, Siddiqui and colleagues performed a 2-phase study of venous angioplasty in individuals with MS and findings of extracranial venous anomalies consistent with CCSVI. Phase 1 was an open-label safety study of 10 subjects and phase 2 was a randomized, sham-controlled, double-blind study of 19 subjects (10 sham procedure, 9 treated). Both phases were 6 months in duration and enrolled individuals from June 2010 to March 2012. Study subjects were assessed at 1, 3, and 6 months post procedure with MRI, clinical and hemodynamic findings. Primary endpoints were safety at 24 hours and 1 month, venous outflow restoration greater than 75% at 1 month, and effect of angioplasty on new lesion activity and relapse rate over 6 months. There were no perioperative complications; however, 1 subject with a history of syncope required placement of a pacemaker prior to discharge due to episodic bradycardia. At 1 month post procedure, the Doppler evidence-based venous hemodynamic insufficiency severity score (VHISS) was reduced more than 75% compared to baseline in phase 1. In phase 2, higher MRI activity and relapse activity were identified as non-significant trends in the treated versus sham arm over 6 months. No differences in other endpoints were observed. The authors concluded that the procedure was reasonably safe, however "it failed to provide any sustained improvement in venous outflow as measured by duplex or clinical and MRI outcomes."

There have been various reports of serious adverse and potentially fatal events occurring as a result of venous angioplasty for the treatment of MS (Doepp, 2010; Kahn, 2010; Qui 2010). Khan (2010) states: "Any invasive endovascular procedures including angioplasty and venous stent placement should be discouraged until there is conclusive evidence to justify their indication in MS."

Mandato and colleagues (2012) evaluated the safety of outpatient endovascular treatment in those with MS and CCSVI. A retrospective analysis was performed to assess complications occurring within 30 days of endovascular treatment of CCSVI. The study was comprised of 240 individuals and 257 procedures

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performed over 8 months. The indication for treatment was symptomatic MS. Primary procedures accounted for 93.0% (239 of 257) of procedures, and repeat interventions accounted for 7% (18 of 257). For individuals treated primarily, 87% (208 of 239) had angioplasty and 11% (26 of 239) had stent placement. Five individuals were not treated. Of those with restenosis, 50% (9 of 18) had angioplasty and 50% (9 of 18) had stent placement. Complications reported in the participants after the procedures included headache in 8.2% (21 of 257) and neck pain in 15.6% (40 of 57); 52.5% (21 of 40) of these individuals underwent stent placement. Three individuals experienced venous thrombosis requiring retreatment within 30 days. Sustained intra-procedural cardiac arrhythmias were observed in 3 individuals with 2 requiring hospitalization. The authors reported that the correlation between MS and CCSVI is a new theory and future research is needed in this area to show the effectiveness of endovascular treatment. This particular study demonstrated the risks of angioplasty and did not assess clinical outcomes after endovascular treatment of CCSVI.

The American Academy of Neurology does not currently address venous angioplasty for the treatment of MS or CCSVI in any of their current MS guidelines. The Cardiovascular and Interventional Radiological Society of Europe (CIRSE) (2010) in a commentary on the treatment of CCSVI indicates there is a lack of evidence for the treatment of CCSVI, stresses the need for randomized trials and advises that this treatment should not be offered to those with MS outside of a well-designed clinical trial.

A matched-pairs pilot study by Arata and Sternberg (2014) described the use of a modified balloon angioplasty technique to the periadvential fibers of the internal jugular, azygos and left renal veins, referred to as transvascular autonomic modulation (TVAM), for treatment of cardiovascular autonomic nervous system (ANS) dysfunction (dysautonomia) to test angioplasty as a means improve ANS function in subjects with MS. The safety and efficacy of TVAM was compared to traditional balloon angioplasty. A total of 21 persons with MS with symptoms of cardiovascular ANS dysfunction underwent TVAM. Subjects in the TVAM group were compared to 21 subjects with MS in the same stages of the disease who underwent venous balloon angioplasty for the treatment of CCSVI. The effect of TVAM on ANS function was determined by assessing heart rate variability at baseline and 24 hours post intervention. The R-R interval values were higher for the TVAM group as compared to the control group, but failed to reach statistical significance for the majority of cardiovascular tests. The safety profile of both procedures was similar. The

authors concluded that the safety and efficacy of TVAM in individuals with MS was encouraging as a treatment of dysautonomia in MS. Limitations noted for this study include a small sample size and a lack of long term and clinical impact.

In 2018, Zamboni and colleagues released the results of the Brain Venous Drainage Exploited Against Multiple Sclerosis (Brave Dreams) trial. This multicenter, randomized, double-blind, sham-controlled, parallel-group trial evaluated the efficacy and safety of venous PTA for CCSVI in subjects with MS. There were 115 subjects included in this trial. Of those subjects, 76 were randomized to the PTA group and 39 were randomized to the sham group. A total of 112 subjects (97.4%) completed the trial including follow-up. The two primary end points at 12 months were a composite of functional impairments (walking control, balance, manual dexterity, postvoid residual urine volume, and visual acuity) and an MRI comparison at 6 and 12 months that evaluated the number of new combined cerebral lesions. Zamboni (2018) stated the following:

> **The functional composite measure did not differ between the PTA and sham groups (41.7% vs 48.7%; odds ratio, 0.75; 95% confidence interval [CI], 0.34-1.68; p=0.49). The mean (SD) number of combined lesions on magnetic resonance imaging at 6 to 12 months were 0.47 (1.19) in the PTA group vs 1.27 (2.65) in the sham group (mean ratio, 0.37; 95% CI, 0.15-0.91; p=0.03: adjusted p=0.09) and were 1.40 (4.21) in the PTA group vs 1.95 (3.73) in the sham group at 0 to 12 months (mean ratio, 0.72; 95% CI, 0.32-1.63; p=0.45; adjusted p=0.45).**

Due to these results, the authors concluded that venous PTA for CCSVI in subjects with MS is safe, but ineffective and, thus, not recommended.

At this time, evidence available in the peer-reviewed published literature does not support the use of venous angioplasty for the treatment MS, CCSVI, or dysautonomia, and use is not in accordance with generally accepted standards of medical practice. Recently published studies are limited by a small sample size and lack of randomization; furthermore, conflicting outcomes have been reported. Results from large randomized controlled clinical trials are needed to further assess the role of this modality in treating MS.

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Ilio-femoral Venous Thrombosis and Chronically Occluded Iliac Vein

Treatment of chronically occluded iliac veins has typically consisted of endovenous bypass. Raju and colleagues (2009) reported on 167 post-thrombotic total iliac occlusions which had been treated with percutaneous recanalization. The procedure was reportedly successful in 129 of 167 limbs (83%). During a 48-month follow-up period, 39 out of 139 stented limbs (28%) occluded. A total of 17 of these individuals had patency restored but 7 later re-occluded. The 4-year secondary stent patency was 66%. While the majority of chronic total occlusions were successfully recanalized with very little morbidity, minimal downtime, sustained long-term stent patency, and substantial clinical improvement, one-third of the study subjects failed to maintain patency.

Kurklinsky and colleagues (2012) retrospectively analyzed 30-day, 1-year and 3-year patency of chronically occluded ilio-femoral venous thrombosis treated with stent placement in a case series from a single institution. Records of 189 consecutive individuals treated by interventional radiology for ilio-femoral venous occlusions between March 1, 2003 and December 1, 2008, were reviewed. A total of 89 cases of chronic iliac or ilio-femoral deep vein thrombosis without involvement of the inferior vena cava met criteria for analysis. All individuals (91 limbs) successfully underwent angioplasty with placement of venous self-expanding stents. Patency rate at discharge was 100%. Following the index procedure, mean pressure gradient across the lesion decreased from 5.63 mm Hg to 0.71 mm Hg. Median follow-up was 11.3 months (range, 0.8-72.4 months). Follow-up at 30 days demonstrated 90 of 91 limbs to be patent. Primary patency rates of treated limbs at 1 and 3 years were 81% and 71%, respectively. Primary patency was lost in 17 cases (19.1%); interventions to maintain or restore stent patency were performed in 13 cases (14.6%). Primary assisted limb patency rates at 1 and 3 years were 94% and 90%, respectively; secondary patency rate was 95%. The authors concluded that angioplasty with stent placement for treatment of chronically thrombosed ilio-femoral veins is a low-risk procedure with acceptable patency rates for as long as 3 years.

A small, prospective randomized trial (Cakir, 2014) compared the efficacy of percutaneous aspiration thrombectomy (PAT) and standard anticoagulant therapy, and anticoagulation alone, for the treatment of acute proximal lower extremity deep vein thrombosis (DVT). A total of 42 subjects with acute proximal iliofemoral DVT were separated into 2 groups: an interventional treatment group (n=21) and an

anticoagulation only treatment group (n=21). After starting standard anticoagulant therapy in the interventional group, PAT with large lumen catheterization was performed. Balloon angioplasty (n=19) and stents (n=14) were used to treat individuals with residual stenosis greater than 50% post PAT. Patency rates and clinical symptoms were evaluated in both the interventional and medical groups at 1, 3 and 12 months after treatment. At 12 months post treatment, the venous patency rates were 57.1% and 4.76% in the interventional and medical treatment groups, respectively. Additionally, a statistically significant improvement was noted in clinical symptom scores of the interventional group with or without stenting as compared to the medical group. The authors concluded that "PAT (with stenting if needed) is a safe and effective method when used to treat proximal DVT" and their findings "suggest that PAT can be used as an alternative treatment in proximal DVT patients."

Razavi and colleagues (2015) performed a systematic review and meta-analysis of stent placement for the treatment of iliofemoral venous outflow obstruction. Data were extracted for multiple disease pathogenesis: nonthrombotic, acute thrombotic (AT) or chronic post-thrombotic (CPT). Main study outcomes included technical success, periprocedural complications (major bleeding, pulmonary embolism, death, and early thrombosis), relief of symptoms at final follow-up, and primary and secondary patency through 5 years. After initial screening for eligibility, 37 studies were included in the review. Technical success rates were comparable among all groups and ranged from 94% in the AT and CPT subjects to 96% in nonthrombotic subjects. The authors reported publication bias for technical success outcomes in AT subjects. Major complications were rare across all groups. Data for relief of symptoms were reported inconsistently. In the nonthrombotic and CPT studies, complete symptom relief at the final follow-up visit was reported for 69%-82% of subjects for pain, 64%-68% of subjects for edema, and 71%-81% of subjects for ulcer healing. Data for symptom relief were rarely reported in subjects with acute DVT. At 1 year follow-up, primary and secondary patency rates were 96% and 99% for nonthrombotic, 87% and 89% for AT, and 79% and 94% for CPT. Primary patency was usually evaluated by duplex ultrasound and a formal definition for primary patency was rarely provided. Inherent study limitations included that data was primarily derived from retrospective case series and there was a lack of complete data available for some comparisons.

A retrospective review of 105 subjects with symptomatic iliocaval venous occlusive lesions was published in 2017 by Rollo and colleagues. The authors evaluated procedural technical success, clinical improvement, and

primary and secondary 1-year patency in the 31 subjects (29.5%) that underwent venous stenting and met inclusion criteria. The results showed 100% of cases had technical success, an overall clinical improvement of 84%, and a primary and secondary 1-year patency success of 66% and 75% respectively using Kaplan-Meier cumulative analysis. The authors concluded that treatment of symptomatic iliocaval venous occlusive lesions with venous stenting is associated with successful 1-year patency; however, it was noted that the study had some limitations, including retrospective design and small sample size.

TORPEDO (Thrombus Obliteration By Rapid Percutaneous Endovenous Intervention In Deep Venous Occlusion) Trial

In a randomized controlled trial, Sharifi and colleagues (2010) compared the safety and efficacy of percutaneous endovenous intervention (PEVI) and anticoagulation versus anticoagulation alone in the reduction of venous thromboembolism (VTE) and post-thrombotic syndrome (PTS) in acute proximal deep venous thrombosis (DVT). A total of 183 individuals with symptomatic proximal DVT were randomized over a 30 month period beginning in February 2007 to receive either PEVI plus anticoagulation, or anticoagulation alone. PEVI consisted of one or more of a combination of thrombectomy, balloon venoplasty, stenting, or local low-dose thrombolytic therapy. In the PEVI group, 68 persons received a balloon venoplasty and 47 stents were placed in 27 persons. Anticoagulation consisted of intravenous unfractionated heparin or subcutaneous low-molecular weight heparin plus warfarin. At 6 months follow-up, recurrent VTE developed in 2 of 88 persons of the PEVI plus anticoagulation group versus 12 of 81 of the anticoagulation-alone group (2.3% vs. 14.8%, p=0.003). PTS developed in 3 of 88 persons of the PEVI plus anticoagulation group and 22 of 81 of the anticoagulation-alone group (3.4% vs. 27.2%, p<0.001). The authors concluded that PEVI plus anticoagulation may be superior to anticoagulation alone in the reduction of VTE and PTS at 6 months and in reducing length of hospital stay and signs and symptoms of DVT.

Follow up results of the TORPEDO trial were reported by Sharifi and colleagues in 2012. Over a mean follow-up of 30±5 months (range 12-41), 3 persons were lost to follow up and there were 11 deaths (5 PE, 6 cancer) which left 88 of 91 persons in the PEVI group and 81 of 92 in the control group. PTS developed at a significantly higher rate in the control group compared to the PEVI group [6 (6.8%) of the PEVI plus anticoagulation group vs. 24 (29.6%)] of the anticoagulation only group (p<0.001). Recurrent VTE

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developed in 4 (4.5%) of the 88 PEVI plus anticoagulation subjects vs. 13 (16%) of the 81 subjects receiving anticoagulation only. The authors concluded that PEVI in persons with proximal DVT appears to be superior to anticoagulation alone in the reduction of VTE and PTS. This benefit extended to more than 30 months.

CaVenT Study

Many persons receiving conventional anticoagulant treatment for acute DVT develop post-thrombotic syndrome (PTS). In an open-label, randomized controlled trial, Enden and colleagues (2012) examined whether additional treatment with catheter-directed thrombolysis (CDT) using alteplase reduced the development of PTS. A total of 209 persons aged 18-75 years with a first-time iliofemoral DVT were recruited from various Norwegian hospitals. Study subjects were randomized within 21 days from symptom onset to conventional anticoagulant treatment alone or additional CDT. Two co-primary outcomes were assessed: frequency of PTS as assessed by Villalta score at 24 months, and iliofemoral patency after 6 months. A total of 209 participants were randomly assigned to treatment groups (108 control, 101 CDT). At completion of 24 months' follow-up, data for clinical status was available for 189 subjects (90%; 99 control, 90 CDT). At 24 months, 37 (41.1%) subjects allocated additional CDT presented with PTS compared to 55 (55.6%) in the control group. The difference in PTS corresponded to an absolute risk reduction of 14.4%, and the number needed to treat was 7. Iliofemoral patency after 6 months was reported in 58 subjects (65.9%) on CDT versus 45 (47.4%) on control. CDT improved clinically relevant long-term outcomes after iliofemoral DVT by reducing PTS compared with conventional treatment. Study limitations included possible local differences due to four different centers having performed the interventions as well as the possibility of bias due to the open-label design of the study.

In a sub analysis of the CaVenT Study, Haig and colleagues (2012) evaluated potential markers for early and long-term efficacy of CDT, adverse events, and their interrelationship. Subjects aged 18-75 years (mean, 54 y; 33 women) with first-time proximal DVT and symptoms up to 21 days were included in an open, multicenter, randomized, controlled trial (CaVenT study). The authors reported on the 92 subjects who received CDT procedures after allocation to the CDT arm in the CaVenT study. The DVT diagnosis was verified by ultrasound or by supplementary venography or CT venography. Anticoagulant therapy was

initiated with low molecular weight heparin. CDT was initiated the next working day, and low molecular weight heparin was subsequently stopped. Adjunctive balloon angioplasty and stent insertion were performed at the operator's discretion to obtain flow and stenosis of less than 50%. Adjunctive balloon angioplasty was performed in 40 subjects. Five subjects, (3 women and 2 men) were diagnosed with May-Thurner syndrome (iliac vein compression) and treated with adjunctive angioplasty, 2 with a balloon only and 3 with stents.

A mean clot resolution of 82% ± 25 was achieved in 92 subjects. Successful lysis (≥ 50%) was obtained in 83 persons. Early efficacy was equal for femoral and iliofemoral thrombus and not related to thrombus load before CDT, symptom duration, or predisposing risk factors. Lower thrombus score at completion of CDT was associated with increased patency at 24 months (p=0.040), and increased patency after 6 and 24 months was correlated with reduced development of PTS after 24 months (p<0.001). The authors concluded that CDT via popliteal access appeared to safely and effectively remove clots and restore iliofemoral patency. No baseline characteristics were associated with early efficacy or PTS after 24 months.

The Society of Interventional Radiology 2009 position statement on the treatment of acute iliofemoral deep vein thrombosis with use of adjunctive catheter-directed intrathrombus thrombolysis states:

> **The Society of Interventional Radiology (SIR) supports the use of anticoagulant therapy for DVT and the use of adjunctive CDT or surgical thrombectomy for patients with limb-threatening phlegmasia. SIR is aware of the controversy within the medical community regarding the use of adjunctive CDT for patients with acute DVT who do not exhibit signs of impending circulatory compromise. SIR recognizes the methodologic limitations of the studies supporting CDT and strongly believes that the execution of a multicenter randomized trial to conclusively quantify the risk–benefit ratio of CDT in patients with acute proximal DVT should be considered an important national health care priority. In the meantime, physicians are still obligated to carefully consider the short-term and long-term consequences of DVT and to recommend the best possible overall treatment strategy to patients based on the currently available, albeit imperfect, evidence. Although there are no large randomized trials to mitigate for or against CDT, the preponderance of the available evidence favors the**

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existence of a clinical benefit to adjunctive CDT for the subset of patients with acute iliofemoral DVT.

The American Heart Association (2011) Recommendations for Percutaneous Transluminal Venous Angioplasty and Stenting, state:

1. **Stent placement in the iliac vein to treat obstructive lesions after CDT, PCDT, or surgical venous thrombectomy is reasonable (Class IIa; Level of Evidence C).**
2. **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).**
3. **The placement of iliac vein stents to reduce PTS symptoms and heal venous ulcers in patients with advanced PTS and iliac vein obstruction is reasonable (Class IIa; Level of Evidence C).**
4. **After venous stent placement, the use of therapeutic anticoagulation with similar dosing, monitoring, and duration as for IFDVT patients without stents is reasonable (Class IIa; Level of Evidence C).**
5. **After venous stent placement, the use of antiplatelet therapy with concomitant anticoagulation in patients perceived to be at high risk of rethrombosis may be considered (Class IIb; Level of Evidence C).**

(Class IIa: Benefit >> risks, Additional studies with focused objectives needed, it is reasonable to perform procedure or administer treatment. Class IIb: Benefit ≥ risks, additional studies with broad objectives needed, additional registry data would be helpful. Procedures/treatment may be considered. Evidence C: very limited populations evaluated, Only consensus opinion of experts, case studies or standards of care.)

The Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS) (Witten, 2015) include the following recommendations:

- **In patients with clinically relevant chronic ilio-caval or ilio-femoral obstruction or in patients with symptomatic non-thrombotic iliac vein lesions, percutaneous transluminal angioplasty and stent placement using large self-expanding stents should be considered. (Class IIa, level B)**
- **Percutaneous transluminal angioplasty is not recommended as a single treatment for patients with chronic deep venous obstruction. (Class III, level C)**
- **After percutaneous transluminal angioplasty stent placement should be considered for patients with chronic deep venous obstruction. (Class IIa, level C)**

(Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy. Class III: Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful. Level B: Data derived from a single randomized clinical trial or large non-randomized studies. Level C: Consensus of opinion of the experts and/or small studies, retrospective studies, registries.)

Emerging studies may suggest improved patency and decreased post thrombotic complications. However, these studies are limited in not isolating the unique contribution to patency and improved outcomes of angioplasty, instead reporting out improvements with angioplasty as one of several catheter directed therapies.

Idiopathic Intracranial Hypertension (IIH)

IIH is also referred to as pseudotumour cerebri or benign intracranial hypertension. It is characterized by an increase in intracranial pressure in the absence of an identifiable cause and may lead to severe headaches and vision loss. The incidence of IIH is higher in young obese women as compared to the general population. Treatment typically includes weight loss, medications, and in some cases, optic nerve fenestration or cerebrospinal fluid shunting procedures. A small case series (Donnet, 2008) consisted of 10 individuals with refractory idiopathic intracranial hypertension who were treated with venous sinus stenting performed with or without angioplasty. The authors indicated that the safety and efficacy of this technique should be further evaluated in a larger series with longer follow-up. Recently, there have been additional small studies published evaluating venous stenting in IIH (Matloob, 2017; Shazly, 2017). All authors concluded venous stenting is an effective treatment for IIH; however, study limitations included small sample sizes and study

designs. A retrospective analysis (Puffer, 2013) assessed outcomes of 143 cases of venous sinus angioplasty with stent placement performed for IIH with a mean follow-up of 22.3 months and reported "promising" results. However, due to sparse documentation of clinical benefit, additional evaluation with long-term follow-up is needed to assess the safety and efficacy of venous sinus angioplasty for IIH.

A systematic review and meta-analysis evaluating the use of venous stenting in individuals with IIH was published by Nicholson and colleagues in 2019. The systematic review yielded 20 studies from 18 centers with a total of 474 individuals. Of the 20 studies, 14 were retrospective and 6 were prospective observational. The largest number of study participants in a single study was 52, while the smallest had 6 participants. All studies were performed at a single center and the mean follow-up period was 18 months. While 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%), there are limitations to these results including no comparator group or randomization in the included studies, small sample sizes, and lack of a standardized tool for clinical evaluation of headache in the included studies. Currently, use of venous stenting for individuals with IIH is not considered in accordance with generally accepted standards of medical practice.

Nutcracker syndrome

Nutcracker syndrome is caused by arterial compression of the left renal vein between the superior mesenteric artery and the aorta (Hartung, 2005). Small case series and retrospective analysis (Chen, 2011; Hartung, 2005; Quevodo, 2014; Wang, 2012) report that endovascular stenting results in increased size of the left renal vein and improved peak velocity flow with improvements in flank pain, hematuria and proteinuria. Both Chen and Wang reported long-term follow-up for individuals at a median of 66 and 36 months, respectively.

Chen and colleagues (2011) retrospectively evaluated the endovascular stenting of 61 individuals with nutcracker syndrome and a median age of 26 years. Symptoms were hematuria, proteinuria or flank pain. Follow-up was completed by clinical exams and duplex ultrasound at 3, 6 and 12 months. Peak velocity in the aortomesenteric portion, and the anteroposterior diameter ratio of the renal hilum and the aortomesenteric

portion of the left renal vein on duplex ultrasound after stenting was significantly decreased compared to that on duplex ultrasound before stenting. Peak velocity in the hilar portion did not statistically differ. Symptoms resolved or improved in 15, 24 and 20 of the 61 individuals within 1 week, and 1 and 6 months, respectively, after endovascular stenting. Symptoms remained unchanged in 2 cases and recurred in 1 case. A perioperative complication was noted in 1 individual, consisting of a stent mistakenly moved and poorly deployed in a left renal vein collateral, requiring operative intervention. Postoperative complications included stent migration into the right atrium, stent protrusion into the inferior vena cava and stent migration into the hilar left renal vein in 1 case each. Study limitations included the retrospective nature of the review. The authors concluded that based on their long-term follow-up, endovascular stenting is a safe, effective procedure in select adults with persistent, severe symptoms that are unresponsive to conservative therapy at 24 months of follow-up.

In a subsequent retrospective review, Wang and colleagues (2012) assessed 30 individuals diagnosed with nutcracker syndrome admitted for endovascular treatment from January 2004 to August 2010. Each subject received one self-expanding metallic stent in the compressed portion of the left renal vein during the operation, and 3 with severe left-sided varicoceles received left gonadal vein embolization. The postoperative follow-up was 12 to 80 months. No perioperative complications occurred. Postoperatively, 2 cases of stent migration were found at 12 months. At 1-month follow-up, subjects improved, including 2 who had persistent but less microscopic hematuria than before treatment. The clinical symptoms of nutcracker syndrome almost disappeared at 3 months after the treatment. All stents were patent at the duplex scan examination, without restenosis, and no secondary recurrence of the symptoms occurred at the end of the follow-up. Study limitations included the retrospective nature of the review. The authors concluded that endovascular treatment is a safe, effective, and minimally invasive technique that provides good long-term patency rates for nutcracker syndrome. Additionally, the authors stated "further experience and follow-up are needed before accepting such a procedure for the superior choice of the treatment for nutcracker syndrome."

Existing evidence from small case series and retrospective studies is currently insufficient to support the use of venous angioplasty as a generally accepted treatment for nutcracker syndrome. Additional study and longer-term follow-up are needed.

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Definitions

Budd-Chiari syndrome: A rare disease characterized by obstruction of outflow from the small hepatic veins to the level of termination of the inferior vena cava.

Idiopathic intracranial hypertension: Occurs when intracranial pressure increases without a reason. Also known as pseudotumor cerebri or benign intracranial hypertension.

Iliac vein compression syndrome (IVCS): IVCS occurs when compression of the iliocaval venous territory is severe enough to inhibit the rate of venous outflow. A definitive diagnosis of IVCS requires demonstration of a stenotic or occlusive venous lesion on vascular imaging and high suspicion that the lesion is the cause of clinical features consistent with venous compression (for example, DVT or history of a DVT, extensive lower extremity swelling, predominance of venous claudication, or stigmata of chronic venous disease such as skin changes or ulceration).

May-Thurner syndrome: A rarely diagnosed iliac vein compression syndrome defined as extrinsic venous compression by the arterial system against bony structures in the iliocaval venous territory, most commonly of the left common iliac vein by the right common iliac artery, which increases the risk of deep vein thrombosis.

Nutcracker syndrome: A rare condition caused by arterial compression of the left renal vein between the superior mesenteric artery and the aorta.

Superior vena cava syndrome: A group of symptoms that occur (often as a result of cancer) when the superior vena cava is blocked (occlusion or vein narrowing [stenosis]). The most common symptoms are coughing, trouble breathing, and swelling in the face, neck, upper body or arms.

Venogram: An X-ray test that takes pictures of blood flow through the veins in a certain area of the body.

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Venous thoracic outlet syndrome (vTOS): A rare disorder caused by compression of peripheral nerves and vascular structures along their course through the upper thoracic aperture to the axilla.

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This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

~~Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.~~

~~Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.~~

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	11/07/2019	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content of SURG.00122 to new clinical utilization management guideline document with the same title.

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