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### **Venous Stents**

**Clinical Guidelines for Medical Necessity Review** 

Version:1.0Effective Date:October 4, 2023

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#### **Guideline Information**:

Specialty Area: Surgical Services Guideline Name: Venous Stents - Single Service

Literature review current through: 10/4/2023Document last updated: 10/4/2023Type: [X] Adult (18+ yo) | [\_] Pediatric (0-17yo)

### **Table of Contents**

Important Notices	2
Table of Contents	3
Medical Necessity Criteria	3
Service: Venous Stent	3
General Guidelines	3
Medical Necessity Criteria	4
Indications	4
Non-Indications	5
Site of Service Criteria	5
Procedure Codes (HCPCS/CPT)	5
Medical Evidence	5
References	6
Clinical Guideline Revision History/Information	8

### **Medical Necessity Criteria**

### Service: Venous Stents

#### **General Guidelines**

- Units, Frequency, & Duration: Once.
- **Criteria for Subsequent Requests:** Repeat imaging with intervention may be appropriate if there is a significant clinical change since the initial imaging study/intervention.
- **Recommended Clinical Approach:** Venous stents are bare metal self-expanding mesh tubes that are placed inside diseased veins in order to treat symptomatic venous outflow obstruction in the iliofemoral venous system (there are currently no FDA-approved drug-eluting stents for the venous system)

"Off-label" use of venous bare metal stents (i.e., the use of a self-expanding venous stent for a non-FDA-approved indication) is a generally accepted treatment for certain clinical conditions including (but not limited to) the following:

- Superior vena cava syndrome
- Central venous stenosis
- Venous thoracic outlet syndrome.<sup>1</sup>
- Nutcracker syndrome
- **Exclusions:** Known allergic reactions to stent material (e.g. nitinol)

### **Medical Necessity Criteria**

Indications

- → Venous Stent placement is considered an appropriate treatment for adults greater than age 18 with ANY of the following diagnoses<sup>2</sup>:
  - Hepatic venous outflow obstruction (e.g., Budd-Chiari syndrome)<sup>3</sup>; OR
  - Thrombotic obstruction of major hepatic veins (e.g., Budd-Chiari Syndrome)<sup>4</sup>; OR
  - Iliac vein compression syndrome (e.g., iliocaval venous outflow tract obstruction, May-Thurner or Cockett syndrome)<sup>5</sup> when ALL of the following are TRUE<sup>6</sup>:
    - The patient is symptomatic with skin or subcutaneous changes; healed or active ulcers (Clinical, Etiology, Anatomy, and Pathophysiology [CEAP] classes 4-6); AND

- The patient does not have a superficial truncal reflux; OR
- Iliocaval venous obstruction<sup>2</sup> or iliofemoral venous obstruction confirmed by Doppler ultrasound, CT or magnetic resonance venography (MRV)<sup>8-9</sup>; OR
- Iliofemoral or iliocaval venous stenosis (greater than 50% of the diameter of the affected vein or residual stenosis of greater than 30% following angioplasty); OR
- Treatment of a stenosis and/or occlusion at the venous anastomosis of synthetic arteriovenous dialysis access; this includes the use of bare metal venous stents and covered stents (e.g., Gore Viabahn endoprostheses)<sup>10</sup>; OR
- Salvage therapy: Self-expanding venous stent placement may also be indicated for ANY of the following:
  - Post-procedure complications including (but not limited to) venous occlusion and/or dissection; **OR**
  - Off-label use of covered stents or stent grafts may be clinically indicated for post-procedure complications in the venous system including venous occlusion, dissection, perforation, pseudoaneurysm and/or arteriovenous fistula formation; **OR**
- Pulmonary vein stenosis resulting from congenital malformation, extrinsic compression, sequelae of radiofrequency ablation (RFA), lung transplantation, or status post repair of Total Anomalous
  Pulmonary Vein Return (TAPVR) confirmed by diagnostic imaging (eg. echocardiography, CTA); OR
- Superior or Inferior Vena Caval Thrombosis including Superior Vena Cava syndrome confirmed by diagnostic imaging (e.g., CT, Doppler, MRI); OR
- Post-radiation venous stenosis confirmed by diagnostic imaging (e.g., CT, Doppler, MRI); OR
- Symptomatic post-traumatic venous stenosis (e.g., central venous catheters or transvenous devices like pacemakers/defibrillators, pacemaker leads, or a history of abdominal and/or pelvic surgery; OR
- Post-operative stenosis or venous narrowing due to repair of congenital cardiac disease confirmed by diagnostic imaging (e.g., Echo, CT, Doppler, MRI); OR
- Suboptimal or failed angioplasty with **ANY** of the following:

- Residual stenosis of more than 30 percent for a vein measured at the narrowest point of the vascular lumen at the site of angioplasty; OR
- More than 50 percent reduction of luminal diameter; **OR**
- Abrupt persistent occlusion/dissection at the angioplasty site; **OR**
- Occlusion elastic recoil or refractory spasm; OR
- Tear with interruption of the integrity of the intima or lumen causing hemorrhage.

**Non-Indications** 

- → Venous Stent for adults greater than age 18 is not considered an appropriate treatment if ANY of the following is TRUE:
  - Known allergic reactions to stent material (e.g., nitinol); OR
  - Prevention of venous stenosis (e.g., asymptomatic and/or no limitation of function)

Site of Service Criteria

Inpatient or Outpatient.

<b>Procedure Codes</b>	(HCPCS/CPT)

HCPCS/CPT Code	Code Description
37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein
37239	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein (List separately in addition to code for primary procedure)

### **Medical Evidence**

Morris et al. (2023) performed a systematic review on the benefit of stenting for inferior vena cava (IVC). The review included 33 studies with 1575 patients; indications for stenting include IVC syndrome, thrombotic disease, Budd–Chiari syndrome, and IVC stenosis following liver transplant. While IVC stenting shows promise to decrease symptoms, additional randomized clinical trials (RCTs) are needed.<sup>2</sup>

Azizi et al. (2020) cite the potential of venous stenting for treating superior vena cava (SVC). Patients responded more favorably to stenting as compared to radiation therapy, including symptoms that symptoms subsided faster. The authors note the need for a standard method to categorize SVC syndrome to assess the level of severity and determine a treatment plan.<sup>13</sup>

### National and Professional Organizations

In 2020, the **American Association for the Study of Liver Diseases (AASLD)** published guidance titled *Vascular Liver Disorders, Portal Vein Thrombosis, and Procedural Bleeding in Patients with Liver Disease.* The AASLD cites a single randomized control trial in support of percutaneous transluminal angioplasty, with or without stenting, to restore hepatic vein outflow.<sup>4</sup>

The **Society of Interventional Radiology** (2023) supports stent placement for patients with iliofemoral venous obstruction; however, further research needs to quantify the risks and benefits.<sup>10</sup>

### References

- 1. Rajendran S, Cai TY, Loa J, et al. Early outcomes using dedicated venous stents in the upper limb of patients with venous thoracic outlet syndrome: A single centre experience. CVIR Endovasc. 2019 Jul 18;2(1):22. doi: 10.1186/s42155-019-0066-0. PMID: 32026125; PMCID: PMC6966406.
- Center for Medicare and Medicaid Services (CMS). Local coverage determination (LCD): Endovenous stenting (L37893). Accessed August 16, 2023. Revision Effective Date December 27, 2020. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LC DId=37893.
- Northup PG, Garcia-Pagan JC, Garcia-Tsao G, et al. Vascular liver disorders, portal vein thrombosis, and procedural bleeding in patients with liver disease: 2020 practice guidance by the American Association for the Study of Liver Diseases. Hepatology. 2021 Jan;73(1):366-413. doi: 10.1002/hep.31646. PMID: 33219529.
- Rössle M. Interventional treatment of Budd-Chiari syndrome. Diagnostics (Basel). 2023 Apr 18;13(8):1458. doi: 10.3390/diagnostics13081458. PMID: 37189559; PMCID: PMC10137827.
- 5. Fereydooni A, Stern JR. Contemporary treatment of May-Thurner Syndrome. J Cardiovasc Surg (Torino). 2021 Oct;62(5):447-455. doi: 10.23736/S0021-9509.21.11889-0. PMID: 33870678.
- 6. Morris RI, Jackson N, Smith A, et al. A systematic review of the safety and efficacy of inferior vena cava stenting. Eur J Vasc Endovasc Surg. 2023 Feb;65(2):298-308. doi: 10.1016/j.ejvs.2022.11.006. PMID: 36334902.
- Hoshino Y, Yokoi H. Venous stenting for postthrombotic iliocaval venous obstructive disease: Clinical efficacy and mid-term outcomes. Ann Vasc Dis. 2022 Dec 25;15(4):275-281. doi: 10.3400/avd.oa.22-00100. PMID: 36644257; PMCID: PMC9816030.
- Razavi MK, Jaff MR, Miller LE. Safety and effectiveness of stent placement for iliofemoral venous outflow obstruction: Systematic review and meta-analysis. Circ Cardiovasc Interv. 2015 Oct;8(10):e002772. doi: 10.1161/CIRCINTERVENTIONS.115.002772. PMID: 26438686.
- Vedantham S, Weinberg I, Desai KR, et al. Society of Interventional Radiology Position statement on the management of chronic iliofemoral venous obstruction with endovascular placement of metallic stents. J Vasc Interv Radiol. 2023 Jun 16;S1051-0443(23)00426-8. doi: 10.1016/j.jvir.2023.06.013. PMID: 37330211.
- 10. MacRae JM, Dipchand C, Canadian Society of Nephrology Vascular Access Work Group, et al. Arteriovenous access failure, stenosis, and thrombosis. Can J Kidney Health Dis. 2016 Sep 27;3:2054358116669126. doi: 10.1177/2054358116669126. PMID: 28270918; PMCID: PMC5332078.

## Clinical Guideline Revision History/Information

Original Date: October 4, 2023		
Review History		