**Prior Authorization Review Panel**
**MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

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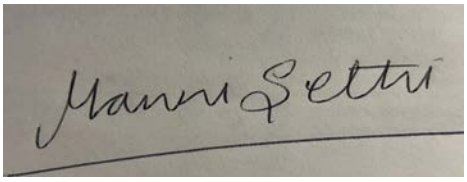
| **Plan: AmeriHealth Caritas Pennsylvania Community Health Choices** | **Submission Date**: 02/22/2023 |
| **Policy Number:** CCP.1320 | **Effective Date:** 9/2017<br>**Revision Date:** September 1, 2022 |
| **Policy Name: Endovenous stents** | |
| **Type of Submission – Check all that apply:**<br><br>☐ **New Policy**<br>**X Revised Policy***<br>☐ **Annual Review – No Revisions**<br>☐ **Statewide PDL** | |
| ***All revisions to the policy must be highlighted using track changes throughout the document.**<br><br>**Please provide any clarifying information for the policy below:**<br><br>Please see revisions with tracked changes below. | |
| **Name of Authorized Individual (Please type or print):**<br><br>Manni Sethi, MD,MBA, CHCQM | **Signature of Authorized Individual:**<br><br>  |

# Endovenous stents

Clinical Policy ID: CCP.1320

Recent review date: 9/2022

Next review date: 1/2024

Policy contains: Deep vein thrombosis, chronic venous disease, endovenous, stent, venous.

*AmeriHealth Caritas Pennsylvania Community HealthChoices has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania Community HealthChoices when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania Community HealthChoices will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are not guarantees of payment.*

## Coverage policy

Placement of endovenous stents for the management of chronic venous disease is clinically proven and, therefore, medically necessary, when all of the following criteria are met (American College of Phlebology, 2015; American College of Radiology, 2019; DeLeve, 2009; Jaff, 2011; Kahn, 2014; Lok, 2020; O'Donnell, 2014):

- Conservative management has failed to improve chronic venous disease.
- Either:
    - Following a suboptimal or failed percutaneous transluminal angioplasty. A suboptimal or failed angioplasty is defined as dilation judged by the physician to be suboptimal or failed due to the presence of unfavorable lesion morphology such as:
        - Residual stenosis of more than 30% for a vein measured at the narrowest point of the vascular lumen at the site of angioplasty or more than 50% reduction of luminal diameter.
        - A tear that interrupts the integrity of the intima or lumen causing hemorrhage.
        - Abrupt persistent occlusion or dissection at the site of angioplasty, occlusion elastic recoil, or refractory spasm.
    - As a planned adjunct to angioplasty when angioplasty alone is not expected to provide a durable result.
- For members with severely symptomatic venous obstructions due to any of the following:

- Iliac vein compression syndrome also known as May-Thurner or Cockett syndrome.
- Iliocaval obstruction.
- Iliofemoral obstruction for patients with venous leg ulceration(s) not relieved by conservative therapies and compression. Progression of symptoms may lead to Phlegmasia Cerulea Dolens, acute inferior vena cava thrombosis, and rapid thrombus extension despite anticoagulation as well as anatomically extensive deep venous thrombosis affecting the common femoral and/or iliac vein, or post-thrombotic stenosis with ankle edema of venous origin (minimum pathophysiological/ Clinical, Etiological, Anatomical, and Pathophysiological score 3).
- Superior or inferior vena caval thrombosis, including superior vena cava syndrome.
- Post-thrombotic syndrome.
- As an adjunct to catheter-directed thrombolysis for acute femoroiliocaval deep vein thrombosis when post thrombolysis imaging identifies symptomatic residual stenosis.
- Post radiation venous stenosis.
- Symptomatic post-traumatic venous stenosis including those resulting from central venous catheters or transvenous leads (e.g., pacemakers or defibrillators) or a history of abdominal and/or pelvic surgery.
- Salvage of thrombosed or stenotic symptomatic or limited function arteriovenous dialysis access fistulae or grafts with compromised venous outflow, failed angioplasty rapid restenosis, or vessel perforation. This may include treatment of trapping a life threatening thrombus, an aneurysm, or pseudoaneurysm that threatens the viability of the arteriovenous fistula or graft, or the treatment of a hemodialysis vascular access rupture that cannot be controlled through balloon tamponade.
- Thrombotic obstruction of major hepatic veins (Budd-Chiari syndrome).
- Transvenous decompression of portosystemic shunts.
- Post-operative stenosis or venous narrowing due to repair of congenital cardiac disease.
- Pulmonary vein stenosis resulting from congenital malformation, extrinsic compression, sequelae of radiofrequency ablation, lung transplantation, or status post repair of total anomalous pulmonary vein return.

Limitations

Placement of endovenous stents for the management of chronic venous disease is investigational/not clinically proven and, therefore, not medically necessary for any indications not listed as a covered indication in the above section, including, but not limited to:

- The placement of a stent in a vein for which there is no objective-related symptom or limitation of function.
- Where presence of local or systemic infection is a relative contraindication to venous stenting, except under unusual circumstances where the benefit of placing the stent may outweigh the risks.
- Use of stents without U.S. Food and Drug Administration approval.
- Stenting of popliteal or tibial veins.

- Venous stenosis less than or equal to 50% of diameter of vein or residual stenosis of less than 30% measured after angioplasty.
- Venous stenting for idiopathic intracranial hypertension.

Alternative covered services (if applicable)

- Dressings for venous ulcers.
- Compression therapy.
- Physiotherapy, leg elevation, and leg massage.
- Pharmacologic treatment.
- Sclerotherapy.
- Transcutaneous laser.
- Endovenous ablation.
- Open surgery.
- Percutaneous transluminal angioplasty alone.

## Background

Chronic venous disease refers to morphological and functional abnormalities of the venous system of long duration that demonstrate symptoms or signs indicating the need for investigation and/or care. The condition affects more than six million U.S. adults. Chronic venous insufficiency describes more advanced forms of venous disorders of the lower extremities, characterized by persistent ambulatory venous hypertension causing various pathologies, including pain, edema, skin changes, and ulcerations (Eberhardt, 2014).

Venous stenosis is intimal hyperplasia and fibrosis causing progressive vessel narrowing and outflow obstruction (Chan, 2004). Venous stenosis most commonly affects the axillary, brachial, cephalic, or brachiocephalic veins of the upper extremities, or the superior vena cava, but can also affect the central veins in the abdomen and the pulmonary artery and veins. Common causes are placement of central venous catheters, pacemaker leads, hemodialysis catheters, prior radiation, trauma, or extrinsic compression.

Pulmonary vein stenosis is a rare condition occurring in young children with or without various forms of congenital heart disease or chronic lung disease. It is caused by an abnormal thickening of the walls in the pulmonary veins (Boston Children's Hospital, 2022). In adults, it is rarer and often associated with mediastinal processes, such as neoplasms or fibrosing mediastinitis, and, increasingly, as a complication of radiofrequency ablation procedures around the pulmonary veins (Pazos-Lopez, 2016).

Unlike arterial disease, in most cases, chronic venous disease seldom poses a threat to limb or life. Consequently, invasive intervention is usually reserved for lesions with disabling symptoms that do not respond to conservative treatment (O'Sullivan, 2015).

An endovenous stent is a synthetic tubular structure implanted in native or graft vasculature to provide mechanical radial support and enhance vessel patency. Percutaneous transluminal angioplasty delivers the stent under ultrasound guidance to the intended location, where it is expanded within the luminal space using either a balloon catheter or a self-expanding mechanism (Oropallo, 2022).

Early venous stenting procedures applied balloon-expandable and self-expandable stents designed for the arterial system as an off-label use. Dedicated venous stents have been developed to address the shortcomings of their arterial counterparts (Oropallo, 2022).

As of this writing, four devices are available for commercial use in the United States under premarket approval, and one is available under an Investigative Device Exemption (U.S. Food and Drug Administration, 2022):

- The Wallstent® Venous Endoprosthesis (Boston Scientific SciMed Inc., Maple Grove, Minnesota) (product code PAF; U.S. Food and Drug Administration, 2001).
- The Vici Venous System® (Veniti Inc., Fremont, California, distributed by Boston Scientific, Marlborough, Massachusetts) available under a Food and Drug Administration Investigational Device Exemption within a clinical trial (clinicaltrials.gov identifier: NCT02112877).
- Fluency® Plus Endovascular Stent Graft (Bard Peripheral Vascular, Inc., Tempe, Arizona).
- Gore Viabahn® Endoprosthesis and Endoprosthesis with Heparin Bioactive Surface (W.L. Gore & Assoc. Inc., Flagstaff, Arizona).
- FLAIR™ Endovascular Stent Graft (Bard Peripheral Vascular, Tempe, Arizona).

In March 2019, Becton, Dickinson, and Company became the first to receive Food and Drug Administration approval to market venous stents to treat iliofemoral venous occlusive disease. The product is called the Venovo® Venous Stent (Journal of Invasive Cardiology, 2019).

## Findings

Several professional guidelines address the medical necessity of endovenous stents (American College of Phlebology, 2015; American College of Radiology, 2019; DeLeve, 2009; Jaff, 2011; Kahn, 2014; Lok, 2020; O'Donnell, 2014). Percutaneous venous angioplasty with stenting is a safe, efficacious, and less invasive alternative to open reconstruction or bypass procedures for treating symptomatic deep vein occlusive disease following thrombolysis to alleviate symptoms and prevent development of post-thrombotic syndrome.

Endovenous stenting is indicated in patients with established post-thrombotic syndrome after previous deep vein thrombosis to reduce symptoms of chronic pain and swelling, to aid ulcer healing in severe cases, and in complex femoral and iliac vein reconstruction. Other indications include venous outflow obstruction for patients with Budd-Chiari Syndrome or May-Thurner syndrome (also called iliac vein compression syndrome), and for patients with central venous stenosis or occlusions following angioplasty failure.

The American College of Phlebology (2015) recommends balloon angioplasty and venous stenting for treatment of thrombotic and nonthrombotic, symptomatic femoroiliocaval vein obstruction not palliated by compression and for patients with impending or active lower extremity venous leg ulceration. Their recommendations are based on evidence showing good to excellent efficacy in terms of stent patency, symptom relief, and recurrent stenosis.

The American Heart Association recommends percutaneous transluminal venous angioplasty and stenting:

- To treat iliofemoral deep vein thrombosis, after catheter-directed thrombolysis, pharmacomechanical catheter-directed thrombolysis, or surgical venous thrombectomy (Jaff, 2011).
- To treat iliocaval or iliofemoral obstruction and prevent rethrombosis and subsequent post-thrombotic syndrome, after catheter-directed thrombolysis or pharmacomechanical catheter-directed thrombolysis (Kahn, 2014).

- In patients with advanced post-thrombotic syndrome and iliac vein obstruction, to reduce post-thrombotic syndrome symptoms and heal venous ulcers, after catheter-directed thrombolysis or pharmacomechanical catheter-directed thrombolysis (Jaff, 2011).
- To aid femoral and iliac vein reconstruction for treatment of post-thrombotic syndrome (Kahn, 2014).

The American College of Radiology (2019) recommends catheter-directed thrombolysis or pharmacomechanical thrombectomy with angioplasty or stenting, in conjunction with anticoagulation therapy, for treatment of obstructive lesions causing moderate-to-severe symptoms. Indications include acute iliofemoral deep vein thrombosis, acute iliofemoral deep vein thrombosis and life-threatening ischemia, iliofemoral deep vein thrombosis with persistent moderate symptoms at least three months after initial anticoagulation treatment, and lesions suggestive of May-Thurner syndrome on cross-sectional imaging.

For vascular disorders of the liver, the American Association for the Study of Liver Diseases recommends angioplasty with or without stenting for patients with Budd-Chiari Syndrome to recanalize the obstructed veins to prevent intestinal infarction and portal hypertension. Patients with focal or segmental obstruction of the hepatic venous outflow tract are theoretically eligible for recanalization (DeLeve, 2009).

The Society for Vascular Surgery and the American Venous Forum recommend venous angioplasty and stenting as an adjunct to standard compression therapy for treatment of inferior vena cava or iliac vein chronic total occlusion or severe stenosis, with or without lower extremity deep venous reflux disease, to aid in venous ulcer healing and to prevent recurrence (O'Donnell, 2014).

The National Kidney Foundation recommends venous stenting for angioplasty failure in symptomatic central venous stenosis or occlusions. Stents should be used with caution (or avoided altogether) in the region of the thoracic outlet due to the potential for extrinsic compression and stent fracture from the overlying structures (Lok, 2020).

Another early, long-term study of stenting to correct obstruction in chronic venous insufficiency (n = 504 over 11 years) revealed no mortality and minor morbidity. Cumulative secondary stent patency was 88% at 5 years; no stent occlusions occurred in non-thrombotic limbs. The proportion of patients with substantial improvement after five years was 78% (for pain) and 55% (for swelling) (Raju, 2010).

A review of about 1,500 patients concluded iliac vein stenting is safe, with morbidity less than 1%. After 3 – 5 years, patency was 90% to 100% for non-thrombotic disease and 74% to 89% for post-thrombotic disease. Relief was 86% to 94% from pain, and 66% to 89% from swelling (Raju, 2013).

A systematic review/meta-analysis of 37 studies (n = 2,869) compared stent efficacy and safety for non-thrombotic, acute thrombotic, and chronic post-thrombotic patients. Technical success rates were comparable among groups (94% to 96%). After one year, primary and secondary patency were 96% and 99% for non-thrombotic, 87% and 89% for acute thrombotic, and 79% and 94% for chronic post-thrombotic patients (Razavi, 2015).

A systematic review/meta-analysis of 14 studies (n = 1,987) found incidence of 30-day thrombotic events after venous stenting was higher in persons with post-thrombotic syndrome than in those with non-thrombotic iliac vein lesions (4.0% versus 0.8%, *P* = .0002). Ulcer healing was greater in persons with non-thrombotic iliac vein lesions (86.9% versus 70.3%, *P* = .0022), and patency rates were lower in those with post-thrombotic syndrome (Wen-da, 2016).

A systematic review and meta-analysis of seven studies (n = 489) assessed endovenous stents for post-thrombotic syndrome with iliofemoral obstruction. Thirty-day complication rates were 3.4% for thrombotic event, 18.1% for per-operative venous injury, and 52.0% for back pain. Other rates were 75.7% for ulcer healing, 52.0%

for pain, and 42.0% for edema relief, prompting authors to declare that endovenous stents can be effective and safe (Qiu, 2019).

A systematic review/meta-analysis of 16 randomized controlled trials (n = 2,011) reviewed six treatments to salvage thrombosed or failing synthetic arteriovenous grafts in patients with end stage renal failure. Stent graft use significantly reduced the risk of failure compared with plain balloon angioplasty (odds ratio 0.53), the only significant difference between treatments at three months (Nikolopoulos, 2019).

A systematic review of nine studies assessed patients with symptomatic iliac vein compression syndrome (n = 953) treated for non-thrombotic iliac vein lesions with stenting (n = 782). Patency rates after stenting were 94.8% - 100% after one month, 88.2% - 94.1% after six months, and 73.4% - 98% after 12 months (Bashar, 2021).

A systematic review/meta-analysis of 16 studies (n = 1,688, 70% of which had post-thrombotic syndrome) of deep venous stenting documented sustained improvements in pain and health-related quality of life. The most common complications were in-stent occlusion (n = 204), in-stent stenosis (n = 149) and minor bleeding (n = 77). Pooled primary/secondary stent patency rates after 12 months were 74.0% and 90.4% (Badesha, 2021).

A systematic review/meta-analysis of five studies (n = 1,050) of patients with iliac vein compression syndrome compared efficacy of stents according to presentation. Primary stent patency after six months was significantly greater in those with non-thrombotic iliac vein lesion versus post-thrombotic syndrome (98.3% versus 90.9%, *P* = .0008). This difference was 94.6% and 84.1% after 12 months (*P* = .0008) (da Silva Rodrigues, 2021).

In 2022, we updated the references and deleted several older references. We added four systematic reviews to the policy that address the safety and efficacy of endovenous stents for deep venous disease.

In a systematic review and meta-analysis of 16 single-arm studies (n = 1,688), participants had post-thrombosis syndrome (70%) or nonthrombotic iliac vein lesions (30%). Other lesion characteristics (e.g., stenotic or occlusive) were reported inconsistently. The pooled primary and secondary stent patency rates at 12 months were 74.0% and 90.4%, respectively. At the last follow-up, 73.4% of ulcers had healed, and improvements in health-related quality of life, pain, venous claudication, and edema after stenting were observed. The incidence of major and minor bleeding was 1.9% and 4.7%, respectively (Badesha, 2022a).

A systematic review of 42 cohort studies (n = 3,429) identified six episodes of stent migration and calculated pooled 12-month primary and secondary iliofemoral stent patency rates of 73.8% and 91.5%, respectively (Badesha, 2022b). The third systematic review of 11 low-quality observational studies found insufficient evidence to support extending venous stents across the inguinal ligament for treating iliac venous obstructions, as stent fracture and stent compression at the inguinal ligament affected stent patency (Machado, 2021).

The fourth systematic review and meta-analysis of 49 studies (n = 5,154) of moderate risk of bias compared the effectiveness of dedicated and nondedicated endovenous stents for treating iliofemoral obstruction. Technical success rates were high in patients with either thrombotic or nonthrombotic venous disease regardless of type of stent used. In patients with nonthrombotic iliac vein lesions, patency rates and clinical outcomes between dedicated and nondedicated endovenous stents were comparable at one year follow-up, but there was insufficient evidence to assess these relative outcomes between groups in patients with acute deep vein thrombosis (Majeed, 2022).

These new results from observational studies suggest venous stents of any type are safe and improve symptoms and health-related quality of life in patients with severe thrombotic and nonthrombotic deep venous disease. Stent patency and complications were generally low but inconsistently reported in studies. These results confirm previous results and warrant no policy changes.

## References

On June 16, 2022, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “chronic venous disease,” “endovenous,” “stent,” and “venous.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.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## Policy updates

7/2017: initial review date and clinical policy effective date: 9/2017

7/2018: Policy references updated.

9/2019: Policy references updated. Policy ID changed to CCP.1320.

9/2020: Policy references updated.

9/2021: Policy references updated.

9/2022: Policy references updated.