AmeriHealth Caritas Ohio

Endovenous stents

Clinical Policy ID: CCP.1320

Recent review date: 9/2024

Next review date: 1/2026

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

AmeriHealth Caritas Ohio has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Ohio's 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, on a case by case basis, by AmeriHealth Caritas Ohio 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 Ohio's 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 Ohio's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Ohio will update its clinical policies as necessary. AmeriHealth Caritas Ohio's 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, may be necessary, when all of the following criteria are met (American College of Phlebology, 2015; American College of Radiology, 2019, 2023;; Kahn, 2014; Lok, 2020; Northup, 2021):

- Placement of endovenous stents for chronic venous disease management is clinically proven and may be necessary when all of the following criteria are met:
- Conservative management has failed to improve the condition.
- Either:
  a) Following a suboptimal or failed percutaneous transluminal angioplasty, as determined by the physician.
  b) 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 (May-Thurner or Cockett syndrome)
- Iliocaval or iliofemoral obstruction
- Superior or inferior vena caval thrombosis
- Post-thrombotic syndrome

- Adjunct to catheter-directed thrombolysis for acute femoroiliocaval deep vein thrombosis
- Post-radiation venous stenosis
- Symptomatic post-traumatic venous stenosis
- Salvage of thrombosed or stenotic symptomatic arteriovenous dialysis access
- Thrombotic obstruction of major hepatic veins (Budd-Chiari syndrome)
- Transvenous decompression of portosystemic shunts
- Post-operative stenosis related to congenital cardiac disease repair
- Pulmonary vein stenosis from various causes

Limitations

Placement of endovenous stents for the management of chronic venous disease is investigational/not clinically proven and, therefore, are considered experimental/investigational and not clinically proven 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 (Agarwal, 2013). 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, and hemodialysis catheters, as well as 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, undated). 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, 2023).

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, 2023).

As of this writing, five iliac vein stents are available for commercial use in the United States under premarket application approval, (U.S. Food and Drug Administration, 2023):

- The Wallstent® Venous Endoprosthesis (Boston Scientific SciMed Inc., Maple Grove, Minnesota)
- The Vici Venous System® (Veniti Inc., Fremont, California, distributed by Boston Scientific, Marlborough, Massachusetts).
- Venovo® Venous Stent (Bard Peripheral Vascular, Inc., Tempe, Arizona).
- Abre Venous Self-expanding Stent System® (Medtronic Vascular, Inc., Plymouth, Minnesota).
- Zilver Vena Venous Self-Expanding Stent® (Cook Ireland Ltd., Limerick, Ireland).

Findings

Guidelines

Several professional guidelines outline the medical necessity of endovenous stents for various venous conditions. The Society of Interventional Radiology recommends stent placement to reduce symptom severity and the risk of re-thrombosis in patients with flow-limiting obstructive lesions in the iliac vein following thrombus debulking, though it notes that well-designed randomized studies are needed to further quantify risks and benefits (Vedantham, 2023). The American College of Phlebology (now the American Vein & Lymphatic Society) advocates for balloon angioplasty and venous stenting in cases of symptomatic femoroiliocaval vein obstruction and acute deep vein thrombosis, supported by evidence of good to excellent efficacy in stent patency and

symptom relief (American College of Phlebology, undated). The American Heart Association endorses percutaneous transluminal venous angioplasty and stenting for a range of conditions, including iliofemoral deep vein thrombosis and advanced post-thrombotic syndrome, emphasizing their role in reducing post-thrombotic syndrome symptoms (Kahn, 2014).

The American College of Radiology in its 2019 guidelines, recommends catheter-directed thrombolysis or pharmacomechanical thrombectomy with angioplasty or stenting in conjunction with anticoagulation therapy for treating obstructive lesions causing moderate-to-severe symptoms, including acute iliofemoral deep vein thrombosis and lesions indicative of May-Thurner syndrome. The 2023 update extends these recommendations to include iliac vein stenting for venous leg ulcers and severe post-thrombotic changes (American College of Radiology, 2019, 2023). For vascular disorders of the liver, the American Association for the Study of Liver Diseases recommends using transjugular intrahepatic portosystemic shunt (TIPS) or direct intrahepatic portosystemic shunt with polytetrafluoroethylene-covered stents as the treatment of choice for hepatic vein thrombosis in Budd-Chiari syndrome when other treatments fail (Northup, 2021). The National Kidney Foundation suggests venous stenting for angioplasty failure in symptomatic central venous stenosis or occlusions, but advises caution in the thoracic outlet region due to potential risks of stent fracture (Lok, 2020).

Systematic Reviews and Meta-Analyses

Iliac Vein Stenting Efficacy and Safety

Several studies have assessed the safety and efficacy of iliac vein stenting across different patient populations. A review of approximately 1,500 patients concluded that iliac vein stenting is safe, with a morbidity rate of less than 1%, and demonstrated high patency rates of 90% to 100% for non-thrombotic disease and 74% to 89% for post-thrombotic disease after 3 to 5 years (Raju, 2013). A systematic review on endovenous stenting in chronic venous disease secondary to iliac vein obstruction, which included 16 studies and 2,431 patients, found successful procedural outcomes in 97.6% of cases, with improvements in chronic venous disease severity and quality of life. However, the overall quality of evidence was rated as low to very low, with major complications occurring in a small percentage of cases (0% to 8.7% per stented limb) (Seager, 2016). A systematic review and meta-analysis of 37 studies (n = 2,869) reported comparable technical success rates among non-thrombotic, acute thrombotic, and chronic post-thrombotic patients (94% to 96%), with primary and secondary patency rates at one year ranging from 79% to 99% (Razavi, 2015).

Post-Thrombotic Syndrome and Stent Outcomes

Studies focused on post-thrombotic syndrome reveal important distinctions in outcomes. A review of 14 studies (n = 1,987) found a higher incidence of thrombotic events in post-thrombotic syndrome patients compared to those with non-thrombotic iliac vein lesions (4.0% vs. 0.8%, P = .0002), alongside greater ulcer healing rates in non-thrombotic lesions (86.9% vs. 70.3%, P = .0022) (Wen-da, 2016). Additionally, a meta-analysis of five studies (n = 1,050) reported significantly higher primary stent patency in non-thrombotic iliac vein lesions compared to post-thrombotic syndrome after six months (98.3% vs. 90.9%, P = .0008) (da Silva Rodrigues, 2021).

Venous Compression Syndromes and Stenting

Systematic reviews have also examined the efficacy of stenting in specific compression syndromes. A review of nine studies (n = 953) focusing on symptomatic iliac vein compression syndrome reported high patency rates following stenting, with primary patency rates ranging from 94.8% to 100% after one month, 88.2% to 94.1% after six months, and 73.4% to 98% after twelve months (Bashar, 2021). For Nutcracker syndrome, a review of 11 retrospective case series compared endovascular stenting (n = 170) to extravascular stenting (n =

63), finding similar rates of symptom resolution and hematuria improvement, though reinterventions were more frequent after endovascular stenting (Fuentes-Perez, 2023).

Pulmonary and Central Vein Stenosis

Stenting has also been evaluated for conditions beyond the iliac veins. In pulmonary vein stenosis, a systematic review of 8 studies (n = 487) found stent implantation to be superior to balloon angioplasty in reducing the risk of restenosis (odds ratio 2.91, 95% confidence interval 1.15 to 7.37, P = .025), though safety outcomes were comparable (Agasthi, 2023). For central vein stenosis, a review of 33 uncontrolled, retrospective studies with a high risk of bias (n = 1,575) found limited evidence supporting inferior vena cava stenting for various indications, though the procedure appears safe with few major adverse events and some improvements in symptoms and quality of life (Morris, 2023).

Complications and Long-Term Outcomes

Long-term outcomes and complications are critical in evaluating stent efficacy. A meta-analysis of 16 studies (n = 1,688) reported pooled primary and secondary stent patency rates at 12 months of 74.0% and 90.4%, respectively, with significant improvements in health-related quality of life and ulcer healing (Badesha, 2022a). However, a systematic review of 11 observational studies highlighted insufficient evidence to support extending venous stents across the inguinal ligament for treating iliac venous obstructions, due to risks of stent fracture and compression at the inguinal ligament (Machado, 2021).

Surveillance and Re-Intervention

Recent evidence emphasizes the importance of surveillance and timely re-intervention to maintain stent patency. Badesha (2024) reported favorable medium- to long-term outcomes of endovenous stenting in chronic deep venous disease, with primary, primary-assisted, and secondary patency rates at 12 months of 83%, 90%, and 95%, respectively. A review by Chawla (2024) of 39 studies (n = 1,539) on superior vena cava, subclavian, and brachiocephalic vein stenosis found that primary patency rates were good up to one year (81.5% at six -12 months) but declined thereafter, highlighting the need for vigilant follow-up.

Comparisons with Other Interventions

Finally, comparisons between stenting and other interventions provide context for treatment decisions. A meta-analysis of 16 randomized controlled trials (n = 2,011) found that stent graft use significantly reduced the risk of failure compared to plain balloon angioplasty in salvaging thrombosed or failing synthetic arteriovenous grafts (Nikolopoulos, 2019). In contrast, a review of 7 randomized controlled trials (n = 1,485) found little to no difference between stent/angiography and best medical practice (anticoagulation) for deep vein thrombosis treatment in terms of post-thrombotic syndrome incidence, venous thromboembolism, major bleeding, or quality of life (Flumignan, 2023).

In 2024, we condensed and reorganized the findings section. We added three new citations that include meta analyses, systematic reviews, and clinical guidelines Seager (2016), Badesha (2024), Chawla (2024.

References

On August 13, 2024, 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.

9/2023: Policy references updated.

9/2024: Policy references updated.