Endovenous stents

Clinical Policy ID: CCP.1320

Recent review date: 9/2021

Next review date: 1/2023

Policy contains: Chronic venous disease, endovenous, stent, venous.

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center'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 by Sandhills Center 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. Sandhills Center 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. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center 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 the following criteria are met:

- Conservative management has failed to improve chronic venous disease
- Percutaneous Transluminal Angioplasty has failed to improve chronic venous disease. 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.
- A stent may be placed as a planned adjunct to angioplasty rather than in response to a suboptimal or failed angioplasty.
- Primary endovenous stenting is justified for situations where angioplasty alone is not expected to provide a durable result.
- Endovenous stents may be placed 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/CEAP 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 device (e.g., pacemakers, defibrillators,) pacemaker leads 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, e.g. sinus venosus Atrial Septal Defect, discordant atrioventricular connection status post Mustard or Senning repair of Transposition of the Great Arteries.
- 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 (Centers for Medicare & Medicaid Services, 2020).

Limitations

Placement of endovenous stents for the management of chronic venous disease are investigational/not clinically proven and, therefore, not medically necessary for any of the following:

- All other uses of endovenous stents not listed as a covered indication in this section.
- The placement of a stent in a vein for which there is no objective-related symptom or limitation of function.
- 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 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 (Centers for Medicare & Medicaid Services, 2020).

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 over 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 arterial stenosis is a congenital abnormality often presenting with other congenital heart or lung defects; it may occur in isolation and be rapidly progressive (Boston Children's Hospital, 2017). Pulmonary vein stenosis is a rare condition occurring in young children with or without various forms of congenital heart disease. 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 (Latson, 2007).

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.

Early venous stenting procedures applied balloon-expandable and self-expandable stents designed for the arterial system as an off-label use (Bjarnason, 2008). Dedicated venous stents have been developed to address the shortcomings of their arterial counterparts (O'Sullivan, 2015). As of this writing, four are available for commercial use in the United States under premarket approval, and one is available under an Investigative Device Exemption (Food and Drug Administration, 2020):

- The Wallstent® Venous Endoprosthesis (Boston Scientific SciMed Inc., Maple Grove, Minnesota) (product code PAF; 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

Ten professional guidelines (American College of Phlebology, 2015; American College of Radiology, 2013; DeLeve, 2009; Feltes, 2011; Jaff, 2011; Kahn, 2014; Mahnken, 2014; National Kidney Foundation, 2006; O'Donnell, 2014; Wittens, 2015) address the issue of medical necessity of endovenous stents.

In May 2019, the Centers for Medicare & Medicaid Services issued a Local Coverage Determination for endovenous stenting for chronic venous disease; the Centers updated the policy in December 2020. The detailed coverage criteria in this document provide the basis for medical necessity in this clinical policy (Centers for Medicare & Medicaid Services, 2020).

An early, long-term study (n = 982 over nine years) reviewed patients with chronic nonmalignant obstructive lesions of the femoroiliocaval vein stented under intravascular ultrasound guidance. After a mean follow-up of 22 months, authors report no mortality within 30 days, and low rates of morbidity and thrombotic events. The cumulative rate of severe in-stent restenosis (>50%) at 72 months occurred in 10% of thrombotic limbs/1% of non-thrombotic limbs, and quality of life scores increased significantly (Neglén, 2007).

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 of two randomized controlled trials and 66 cohort studies (n = 46,728) of patients undergoing carotid artery stents found that Wallstents were significantly less likely (*P* = .03) than Acculink stents to result in a short-term major adverse effect (de Vries, 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 failure of end stage renal disease. Stent graft use significantly reduced the risk of failure compared with plain balloon angioplasty (OR 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).

References

On June 8, 2021, 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.

American College of Phlebology, Practice Guidelines: Chronic deep venous obstruction of the femoroiliocaval venous system. 2015:1-8. http://www.phlebology.org/wp-content/uploads/2015/10/Management-of-Obstruction-of-the-Femoroiliocaval-Venous-System-Guidelines.pdf.

American College of Radiology. ACR Appropriateness Criteria® radiologic management of iliofemoral venous thrombosis. https://acsearch.acr.org/docs/3082663/Narrative. Revised 2019.

Badesha AS, Bains PRS, Bains BRS, Khan T. A systematic review and meta-analysis of the treatment of obstructive chronic deep venous disease using dedicated venous stents. *J Vasc Surg Venous Lymphat Disord*. 2021 May 6;S2213-333X(21)00210-9. Doi: 10.1016/j.jvsv.2021.04.014.

Bashar K, Shalan A, Ali SS, Tang T, Tiwari A. Endovascular versus medical treatment of venous compression syndrome of the iliac vein – a systematic review. *Vasa*. 2021;50(1):22-29. Doi: 10.1024/0301-1526/a000911.

Bjarnason H. Chapter 45 Endovascular reconstruction of complex iliocaval venous occlusions. Stent selection. In: Gloviczki P, ed. *Handbook of Venous Disorders: Guidelines of the American Venous Forum Third Edition*. Boca Raton, Florida: Taylor & Francis Group; 2008:509-510.

Boston Children's Hospital. Pulmonary Vein Stenosis Symptoms & Causes. . http://www.childrenshospital.org/conditions-and-treatments/conditions/pulmonary-vein-stenosis/symptoms-and-causes. Published 2017.

Chan AW, Chi YW. Venous stenosis. In: Bhatt DL, editor. Guide to peripheral and cerebrovascular intervention. Remedica. https://www.ncbi.nlm.nih.gov/books/NBK27375/. Published 2004.

Centers for Medicare & Medicaid Services. Local Coverage Determination L37893. Endovenous stenting. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37893&ver=30&name=331*1&UpdatePeriod=911&bc=AEAABAAAAAAA&. Last revised December 27, 2020.

Da Silva Rodrigues L, Bertanha M, El Dib R, Moura R. Association between deep vein thrombosis and stent patency I symptomatic iliac vein compression syndrome: Systematic review and meta-analysis. *J Vasc Surg Venous Lymphat Disord*. 2021;9(1):275-284. Doi: 10.1016/j.jvsv.2020.08.022.

DeLeve LD, Valla DC, Garcia-Tsao G. Vascular disorders of the liver. *Hepatology.* 2009;49(5):1729-1764. Doi: 10.1002/hep.22772.

De Vries EE, Meershoek AJA, Vonken EJ, den Ruijter HM, van den Berg JC, de Borst GJ, ENDORSE Study Group. A meta-analysis of the effect of stent design on clinical and radiologic outcomes of carotid artery stenting. *J Vasc Surg*. 2019;69(6):1952-1961.e1. Doi: 10.1016/j.jvs.2018.11.017.

Eberhardt RT, Raffetto JD. Chronic venous insufficiency. *Circulation.* 2014; 130(4):333-346. Doi: 10.1161/circulationaha.113.006898.

El Kassem M, Alghamdi I, Vazquez-Padron RI, et al. The role of endovascular stents in dialysis access maintenance. *Adv Chronic Kidney Dis.* 2015;22(6):453-458. Doi: 10.1053/j.ackd.2015.02.001.

Food and Drug Administration. Premarket Approval database search using product codes MAF, MIH, NIM, NIN, NIO, NIP, and PFV. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Last updated June 7, 2021.

Food and Drug Administration. Summary of safety and effectiveness data. WALLSTENT® Venous Endoprosthesis with Unistep™ Plus Delivery System. PMA Number P980033. https://www.accessdata.fda.gov/cdrh_docs/pdf/p980033b.pdf. Published November 16, 2001.

Jaff MR, McMurtry MS, Archer SL, et al. American Heart Association Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; American Heart Association Council on Peripheral Vascular Disease; American Heart Association Council on Arteriosclerosis, Thrombosis, and Vascular Biology. Management of massive and submassive pulmonary embolism, iliofemoral deep vein thrombosis, and chronic thromboembolic pulmonary hypertension: a scientific statement from the *American Heart Association. Circulation*. 2011;123:1788-1830. Doi: 10.1161/CIR.0b013e318214914f.

Journal of Invasive Cardiology. BD Receives U.S. FDA Approval for First Venous Stent to Treat Iliofemoral Venous Occlusive Disease. https://www.invasivecardiology.com/news/bd-receives-us-fda-approval-first-venous-stent-treat-iliofemoral-venous-occlusive-disease. Published March 14, 2019.

Kahn SR, Comerota AJ, Cushman M, et al. The postthrombotic syndrome: evidence-based prevention, diagnosis, and treatment strategies: a scientific statement from the American Heart Association. *Circulation.* 2014;130(18):1636-1661. Doi: 10.1161/cir.0000000000000130.

Latson LA, Prieto LR. Congenital and acquired pulmonary vein stenosis. *Circulation.* 2007;115(1):103-108. Doi: 10.1161/CIRCULATIONAHA.106.646166.

Mahnken AH, Thomson K, de Haan M, et al. CIRSE standards of practice guidelines on iliocaval stenting. *Cardiovasc Intervent Radiol*. 2014;37: 889-897. Doi: 10.1007/s00270-014-0875-4.

National Kidney Foundation. KDOQI clinical practice guidelines and clinical practice recommendations for 2006 updates: hemodialysis adequacy, peritoneal dialysis adequacy and vascular access. *Am J Kidney Dis.* 2006;48:S1-S322(suppl 321). https://www.kidney.org/sites/default/files/docs/12-50-0210_jag_dcp_guidelines-va_oct06_sectionc_ofc.pdf.

National Kidney Foundation. KDOQI clinical practice guideline for hemodialysis adequacy: 2015 update. *Am J Kidney Dis*. 2015;66(5):884-930. Doi: 10.1053/j.ajkd.2015.07.015.

Neglén P, Hollis KC, Olivier J, et al. Stenting of the venous outflow in chronic venous disease: Long-term stent-related outcome, clinical, and hemodynamic result. *J Vasc Surg.* 2007;46: 979-990.

Nikolopoulos GK, Yiallourou AI, Argyriou, Bonovas S, Georgiadis GS, Lazarides MK. Short term success of treatments to salvage thrombosed or failing synthetic arteriovenous grafts in End Stage Renal Disease: A systematic review and network meta-analysis of randomised controlled trials. *Eur J Vasc Endovasc Surg*. 2019;58(6):921-928. Doi: 10.1016/j.ejvs.2019.06.495.

O'Donnell TF, Jr., Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg.* 2014;60(2): 3S-59S. Doi: 10.1016/j.jvs.2014.04.049.

O'Sullivan G. Current Trends in Venous Stenting. Endovascular Today. http://evtoday.com/2015/07/current-trends-in-venous-stenting/. Published July 2015.

Qiu P, Zha B, Xu A, et al. Systematic review and meta-analysis of iliofemoral stenting for post-thrombotic

syndrome. *Eur J Vasc Endovasc Surg*. 2019;57(3):407-416. Doi: 10.1016/j.ejvs.2018.09.022.

Raju S, Razavi MK, Spencer B, Williams DM. Venous Stenting: Expectations and Reservations. Endovascular Today. http://evtoday.com/2013/07/venous-stenting-expectations-and-reservations/. Published July 2013.

Raju S, Darcey R, Neglen P. Unexpected major role for venous stenting in deep reflux disease. *J Vasc Surg.* 2010;51:401-409. Doi: 10.1016/j.jvs.2009.08.032.

Raju S. Best management options for chronic iliac vein stenosis and occlusion. *J Vasc Surg*. 2013;57:1163–1169. Doi: 10.1016/j.jvs.2012.11.084.

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;8(10):e002772. Doi: 10.1161/circinterventions.115.002772.

Wen-da W, Yu Z, Yue-Xin C. Stenting for chronic obstructive venous disease: A current comprehensive meta-analysis and systematic review. *Phlebology*. 2016;31(6):376-389. Doi: 10.1177/0268355515596474.

Wittens C, Davies AH, Baekgaard N, et al. Editor's Choice - Management of chronic venous disease: clinical practice guidelines of the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg.* 2015;49(6):678-737. Doi: 10.1016/j.ejvs.2015.02.007.

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.