

Geisinger Health Plan Policies and Procedure Manual

Policy: MP033

Section: Medical Benefit Policy

Subject: Varicose Vein Treatments

Applicable Lines of Business

Commercial	Х	CHIP	Х
Medicare	Χ	ACA	X
Medicaid	Х		

I. Policy: Varicose Vein Treatments

II. Purpose/Objective:

To provide a policy of coverage regarding varicose vein treatments including sclerotherapy and surgical interventions

III. Responsibility:

A. Medical Directors

B. Medical Management

IV. Required Definitions

- 1. Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. Reviewed the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury:
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

- illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking
 into account both the functional capacity of the Member and those functional capacities that are appropriate for
 Members of the same age

Telangiectases – (Spider veins, web veins, thread veins) are permanently dilated blood vessels that create fine, red lesions or lines with radiating limbs on the skin.

Varicose veins- are large, superficial veins that have become tortuous, dilated, and elongated. They are usually caused by incompetence of the valvular system within the vein. In severe cases, they can cause pain and swelling of the extremity.

DESCRIPTION:

Treatment of varicose veins that have not responded to conservative management such as compression stockings, and have resulted in recurrent superficial thrombophlebitis, severe and persistent pain and swelling, hemorrhage from a ruptured superficial varicosity, or intractable ulceration secondary to venous stasis, can be treated by sclerotherapy, ligation and excision (stripping).

Sclerotherapy involves injection of an inflammatory agent, known as a sclerosant or sclerosing agent, which results in irritation and damage to the lining and tissue of the vein wall. This damage results in hardening or sclerosing of the vein, which eventually results in reabsorption.

The goal of surgical therapy is to improve venous circulation by correcting venous insufficiency through the removal of major reflux pathways.

INDICATIONS: REQUIRES PRIOR AUTHORIZATION by a Geisinger Health Plan Medical Director or designee

Liquid or Foam Sclerotherapy (including Varithena™), Mechanochemical Ablation (MOCA (e.g. ClariVein®) or Stab Phlebectomy, or a combination of both may be considered medically necessary for the treatment of symptomatic varicose tributaries, accessory, and perforator veins when the following criteria are met:

Medical record documentation of Duplex ultrasound or Doppler imaging validation of clinically significant venous insufficiency* **AND** at least one of the following:

- Hemorrhage from venous varicosity; OR
- Venous stasis ulceration; OR
- Superficial phlebitis; OR
- Medical complications of venous insufficiency such as:
 - Documented symptoms of venous insufficiency of the lower extremities such as itching, burning or edema that interferes with activities of daily living and represents a functional impairment, or pain that has failed to respond to a trial of nonprescription or prescription analgesics;

AND

 Documentation of a trial of at least three months of conservative, non-operative treatment including, but not limited to, compliance with compressive stockings providing 20- 30 mm Hg pressure.

*Note: Venous insufficiency is generally defined as outward flow of the saphenous vein lasting greater than or equal to 500 milliseconds or greater than or equal to 350 milliseconds for perforator veins. While documentation of venous insufficiency is adequate to satisfy the authorization requirement, actual values may be used for auditing purposes.

Requests for sclerotherapy (initial treatment or repeat treatment) must be accompanied by a detailed treatment plan, including history and documentation of failed non-invasive treatments, Photographs may be requested at the Plan's discretion. Initially, 1 to 3 sclerotherapy sessions for both legs are considered medically necessary for insured individuals who meet criteria. Up to 20 injections in each leg may be administered in any one session. Requests for additional sclerotherapy sessions are subject to medical necessity review and must include resubmission of updated medical records to include information to clarify if the intended treatment site is new, a recurrence, or a failure of previous therapy.

Vein stripping, ligation, endovenous radiofrequency or laser ablation, excision, cyanoacrylate-based therapy** (e.g., VenaSeal ™) or transilluminated powered phlebectomy of the great saphenous vein, small saphenous vein or both, or perforator veins, may be considered medically necessary when the following criteria are met:

 Duplex ultrasound or Doppler imaging validation of clinically significant venous insufficiency indicated by outward flow of the saphenous vein lasting greater than or equal to 500 milliseconds, or greater than or equal to 350 milliseconds for perforator veins; AND

- At least **one** of the following is exhibited:
 - Severe and persistent pain and swelling interfering with activities of daily living and/or requiring chronic analgesic medication; or
 - o Recurrent phlebitis or thrombophlebitis; or
 - Intractable ulceration, recurrent cellulitis, or continuous stasis dermatitis secondary to venous insufficiency; or
 - o More than one episode of minor hemorrhage from a ruptured superficial varicosity; or
 - o A single significant hemorrhage from a ruptured venous varicosity.

*NOTE: A trial of conservative management is not required for insured individuals who meet criteria for saphenous vein ablation, or who have persistent or recurrent varicosities and have undergone prior endovenous catheter ablation procedures or stripping/division/ligation in the same leg. Conservative management is unlikely to be successful in this population.

**NOTE: For Medicaid Business Segment - cyanoacrylate-based therapy (cpt codes 36482, 36483) requires a Program Exception

Requests for vein stripping, ligation, endovenous radiofrequency or laser obliteration, or transilluminated powered phlebectomy invasive varicose vein therapies (initial treatment or repeat treatment) must be accompanied by a detailed treatment plan, including history and documentation of failed non-invasive treatments. Photographs may be requested at the Plan's discretion. Requests for repeat treatment are subject to medical necessity review and must include resubmission of updated medical records to include information to clarify if the intended treatment site is new, a recurrence, or a failure of previous therapy.

Subfascial Endoscopic Perforator Surgery (SEPS) may be considered medically necessary for the treatment of advanced chronic venous insufficiency secondary to primary valvular incompetence of superficial and perforator veins, with or without deep venous incompetence, when the following criteria are met:

- Medical record documentations of Duplex ultrasound or Doppler imaging validation of clinically significant venous insufficiency* AND
- Perforator vein is greater than or equal to 3.5 mm; AND
- Is located beneath an open or healed venous ulcer

*Note: Venous insufficiency is generally defined as outward flow of the saphenous vein lasting greater than or equal to 500 milliseconds or greater than or equal to 350 milliseconds for perforator veins. While documentation of venous insufficiency is adequate to satisfy the authorization requirement, actual values may be used for auditing purposes.

CONTRAINDICATIONS:

Sclerotherapy is contraindicated in the presence of any of the following:

- Uncontrolled diabetes
- Pregnancy
- Inability to ambulate
- Significant incompetence of the saphenofemoral or saphenopopliteal junctions
- Acute deep vein thrombosis or thrombophlebitis

EXCLUSIONS:

Sclerotherapy and/or surgical interventions for the treatment of varicose veins less than 3 mm are considered cosmetic and are **NOT COVERED.** Sclerotherapy for treatment of telangiectasias and/or surgical intervention for treatment of varicose veins, performed primarily for cosmetic purposes from which no significantly improved physiologic function could be reasonably expected are **Excluded** per the line of business specific benefit documents for commercial lines of business and LCD L27539 for GOLD, and is **NOT COVERED.**

Sclerotherapy is considered experimental and investigational for treatment of the saphenofemoral junction or the saphenous veins because sclerotherapy has not been proven to be effective for treatment of these large veins. Sclerotherapy alone has not been shown to be effective for persons with reflux at the saphenofemoral or saphenopopliteal junctions; under established guidelines, individuals with reflux should also be treated with endovenous ablation, ligation or division of the junction to reduce the risk of varicose vein recurrence.

Photothermal sclerosis (ie. Photoderm Vasculight) is considered **experimental, investigational and unproven**. and is **NOT COVERED.** The effectiveness of this procedure has not been established in the current peer-reviewed published medical literature.

Laser treatment of telangiectasias is considered cosmetic and NOT COVERED.

Cryostripping, (including cryoablation, cryofreezing) of any vein is considered **experimental, investigational and unproven** and is **NOT COVERED.** The effectiveness of this procedure has not been established in the current peer-reviewed published medical literature

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Varicose Vein Treatment

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 0524T Endonevous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring.
- 36299 Unlisted procedure, vascular injection
- 36465 injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein
- 36466 multiple incompetent truncal veins; same leg
- 36468 single or multiple injections of sclerosing solutions, spider veins (telangiectasias); limb or trunk
- 36470 Injection of sclerosing solution; single vein
- 36471 multiple veins, same leg
- 36473 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
- Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
- 36475 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
- 36476 second and subsequent veins in a single extremity, each through a separate access site
- 36478 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
- 36479 second and subsequent veins in a single extremity, each through a separate access site
- Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
- Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites
- 37241 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage
- 37242 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor
- 37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping; and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infraction
- 37244 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation
- 37500 Vascular endoscopy, surgical, with ligation/ perforator veins, subfascial (SEPS)
- 37700 Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions

- 37718 Ligation, division and stripping, short saphenous vein
- 37722 Ligation, division and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below
- 37735 Ligation and division and complete stripping of long and short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
- 37760 Ligation of perforators, subfascial, radical, with or without skin graft
- 37761 Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg
- 37765 Stab phlebectomy of varicose veins, one extremity; 10-20 stab incisions
- more than 20 incisions
- 37780 Ligation and division of short saphenous vein at sapheno-popliteal junction (separate procedure)
- 37785 Ligation, division, and/or excision of varicose vein cluster(s), one leg
- 37799 Unlisted procedure, vascular surgery
- 93970 Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study
- 93971 duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited Study

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

London NJM, Nash R, "Varicose Veins", British Medical Journal, Vol 320(7246), 20 May 2000, pp 1391-1394.

De Cossart L, "Varicose Veins and Pregnancy", British Journal of Surgery, Vol 88(3), Mar 2001, pp 323-324. Lyon RT; Veith FJ; Bolton L; Machado F; "Clinical Benchmark for Healing Chronic Venous Ulcers", The American Journal of Surgery, Vol 176(2), Aug 1998, pp 172-175.

Bello M; Scriven M; Hartshorne T; Bell PRF; Naylor AR; London NJM; "Role of Superficial Venous Surgery in the Treatment of Venous Ulceration" The British Journal of Surgery, Vol 86(6), June 1999, pp 755-759.

The Merck Manual of Diagnosis and Therapy, Section 16. Cardiovascular Disorders, Chapter 212. Peripheral Vascular Disorders.

Feied C; Weiss R, "Varicose Veins and Spider Veins", eMedicine Journal, Vol 2(6), 16 June 2001.

Smookler A; Aloi M;"Varicose Veins", eMedicine Consumer Journal, Vol 2(4), 1 April 2001.

Valencia IC; Falabella A; Kirsner RS; Eaglstein WH; "Chronic Venous Insufficiency and Venous Leg Ulceration", Journal of the American Academy of Dermatology, Vol 44(3), Mar 2001, pp. 401-421.

ECRI, Hotline Response, "Surgical Ligation and Stripping for Varicose Veins", http://www.ecri.org. Accessed 1/7/03.

ECRI, <u>Hotline Response</u>, "Sclerotherapy for the Treatment of Varicose Veins", http://www.ecri.org. Accessed 1/7/03.

Winifred S. Hayes, Inc., Hayes Directory. "Sclerotherapy for symptomatic varicose veins." May 2000; SCLE0701.08: 1-13.

Geisinger Technology Assessment Committee, Triage Group. "Transilluminated Powered Phlebectomy". Reviewed 5/15/03. Re-reviewed 6/04.

Geisinger Technology Assessment Committee, Triage Group. "Endovenous Radiofrequency Obliteration of Saphenous Vein Reflux". Reviewed 8/22/03.

Goldman MP, "Treatment of varicose and telangiectatic leg veins: double-blind prospective comparative trial between aethoxyskerol and sotradecol", Dermatologic Surgery 28(1):52 Jan. 2002.

DeRoos KP, Neiman FHM, Neumann HAM, "Ambulatory phlebectomy versus compression sclerotherapy: results of a randomized controlled trial", Dermatologic Surgery 29(3):221-226. Mar. 2003.

Feied CF, "Sclerosing Solutions", The American College of Phlebology. http://www.phlebology.org/docmechanism.htm

Kanter A, "Technique for Sclerosing Varicose Veins", American College of Phlebology. http://www.phlebology.org/syllabus7.htm

American Academy of Dermatology Association, Guidelines of Care for Sclerotherapy Treatment of Varicose and Telangiectatic Veins. http://www.aasassociation.org/Guidelines/sclero.html

McDonagh B, Sorenson S, Gray C, et. al., "Clinical spectrum of recurrent postoperative varicose veins and efficacy of sclerotherapy management using the compass technique", Phlebology 18(4):173-185. Dec 2003.

Consensus Conference on Sclerotherapy of Varicose Veins of the Lower Limbs. Phlebology 12;2-16. 1997.

Green D., "Sclerotherapy for the permanent eradication of varicose veins: Theoretical and practical considerations", Journal of the American Academy of Dermatology 38(3):461-475. 1998.

Tisi PV, Beverley CA, "Injection sclerotherapy for varicose veins" The Cochrane Library, Issue 1, 2004.

Kalra M, Gloviczki P, Noel AA, Rook TW, Lewis BD, Jenkins GD, Canton LG, Panneton. Subfascial Endoscopic perforator vein surgery in patients with post-thrombotic venous insufficiency – is it justified? Vasc Endovascular Surg. 2002 Jan-Feb;36(1):41-50.

Baron HC, Wayne MG, Santiago C, Lown I, Castellano M, Cioroiu, and Grossi R. treatment of severre chronic venous insufficiency using the subfascial Endoscopic perforator vein procedure. Surg Endosc (2005);19:126-129.

Ting AC, Cheng ST, Ho P, Poon JT, Wu LH, Cheung G. Reduction in deep vein reflux after concomitant subfascial Endoscopic perforating vein surgery and superficial vein ablation in advanced primary chronic venous insufficiency. J Vasc Surg 2006;43:546-50.

Winifred S. Hayes Inc. HAYES Directory. Endoluminal Radiofrequency Ablation for Varicose Veins of the leg. May 16, 2006.

Evidence Based Medicine Guidelines, 22.11.2004. Varicose veins and venous insufficiency of the lower limbs. http://ebmg.wiley.com/ebmg/ltk.NaytaArtikkeli?p_artikkeli=ebm00964

Hirai M, Iwata H, Hayakawa N. Effects of elastic compression stockings in patients with varicose veins and health controls measured by strain gauge plethysmograpy. Skin Research and Technology Nov 2002; 8(4):236.

Klem TM, Schnater JM, Schütte PR, Hop W, van der Ham AC, Wittens CH.. A randomized trial of cryo stripping versus conventional stripping of the great saphenous vein. J Vasc Surg. 2009 Feb;49(2):403-9.

Disselhoff BC, der Kinderen DJ, Kelder JC, Moll FL. Randomized clinical trial comparing endovenous laser with cryostripping for great saphenous varicose veins. Br J Surg. 2008 Oct;95(10):1232-8.

Menyhei G, Gyevnár Z, Arató E, Kelemen O, Kollár L. Conventional stripping versus cryostripping: a prospective randomised trial to compare improvement in quality of life and complications. Eur J Vasc Endovasc Surg. 2008 Feb;35(2):218-23.

Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML, Lohr JM, McLafferty RB, Meissner MH, Murad MH, Padberg FT, Pappas PJ, Passman MA, Raffetto JD, Vasquez MA, Wakefield TW; Society for Vascular Surgery; American Venous Forum. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2011 May;53(5 Suppl):2S-48S.

Hayes. Search & Summary ClariVein Occlusion Catheter, Nonthermal Vein Ablation System (Vascular Insights LLC) for Varicose Veins. November 7, 2013

Mueller RL, Raines JK. ClariVein mechanochemical ablation: background and procedural details. Vasc Endovascular Surg. 2013 Apr;47(3):195-206

van Eekeren RR1, Boersma D, Elias S, Holewijn S, Werson DA, de Vries JP, Reijnen MM Endovenous mechanochemical ablation of great saphenous vein incompetence using the ClariVein device: a safety study. J Endovasc Ther. 2011 Jun;18(3):328-34.

The Medical Letter on Drugs and Therapeutics. Polidocanol (Varithena) for Varicose Veins. Issue 1474, Aug. 3, 2015

Carugo D et al. Benefits of polidocanol endovenous microfoam (Varithena) compared with physician-compounded foams. Phlebology 2015 Jun 1 (epub).

Todd KL, et al. The VANISH-2 study: a randomized, blinded, multicenter study to evaluate the efficacy and safety of polidocanol endovenous microfoam 0.5% and 1.0% compared with placebo for the treatment of saphenofemoral junction incompetence. Phlebology 2014; 29:608.

Gibson K, Ferris B. Cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of post-procedure compression: Initial outcomes of a post-market evaluation of the VenaSeal System (the WAVES Study). Vascular. 2017 Apr;25(2):149-156

Almeida JI, Javier JJ, Mackay EG, et al. Two-year follow-up of first human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. Phlebology. 2015 Jul;30(6):397-404.

Almeida JI, Javier JJ, Mackay EG, Baustista C, Cher DJ, Probestle TM. Thirtysixth- month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. J Vasc Surg: Venous and Lym Dis. 2017;1-9

The European multicenter study on cyanoacrylate embolization of refluxing great saphenous Veins without Tumescent Anesthesia and without Compression Therapy. J Vasc Surg Venous Lymphat Disord. 2013;1(1):101.

Proebstle TM, Alm J, Dimitri S, et al. The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins. J Vasc Surg Venous Lymphat Disord. 2015;3(1):2-7.

Kolluri R, Gibson K, Cher D, Madsen M, Weiss R, Morrison N. Roll-in phase analysis of clinical study of cyanoacrylate closure for incompetent great saphenous veins. J Vasc Surg Venous Lymphat Disord. 2016;4(4):407-415.

Toonder IM, Lam YL, Lawson J, Wittens CH. Cyanoacrylate adhesive perforator embolization (CAPE) of incompetent perforating veins of the leg,a feasibility study. Phlebology. 2014;29(1S):49–54.

Chan YC, Law Y, Cheung GC, Ting AC, Cheng SW. Cyanoacrylate glue used to treat great saphenous reflux: Measures of outcome. Phlebology. 2017;32(2):99-106.

Chan YC, Law Y, Cheung GC, Cheng SW. Predictors of recanalization for incompetent great saphenous veins treated with cyanoacrylate glue. J Vasc Interv Radiol. 2017;28(5):665-671

Bozkurt AK, Yılmaz MF. A prospective comparison of a new cyanoacrylate glue and laser ablation for the treatment of venous insufficiency. Phlebology. 2016 Mar;31(1 Suppl):106-13.

Morrison N, Gibson K, McEnroe S, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). J Vasc Surg. 2015 Apr;61(4):985-94.

Morrison N, Gibson K, Vasquez M, et al. VeClose trial 12-month outcomes of cyanoacrylate closure versus radiofrequency ablation for incompetent great saphenous veins. J Vasc Surg Venous Lymphat Disord. 2017 May;5(3):321-330.

Vähäaho S, Halmesmäki K, Albäck A, et al. Five-year follow-up of a randomized clinical trial comparing open surgery, foam sclerotherapy and endovenous laser ablation for great saphenous varicose veins. Br J Surg. 2018 May;105(6):686-691.

Morrison N, Kolluri R, Vasquez M, et al. Comparison of cyanoacrylate closure and radiofrequency ablation for the treatment of incompetent great saphenous veins: 36-month outcomes of the VeClose randomized controlled trial. Phlebology. 2018 Nov 7:268355518810259.

Gibson K, Morrison N, Kolluri R, et al. Twenty-four month results from a randomized trial of cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. J Vasc Surg Venous Lymphat Disord. 2018a Sep;6(5):606-613.

Gibson K, Minjarez R, Gunderson K, et al. Need for adjunctive procedures following cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of postprocedure compression: Three-month data from a postmarket evaluation of the VenaSeal System (the WAVES Study). Phlebology. 2018b Sep 18:268355518801641.

Brittenden J, Cooper D, Dimitrova M, et al. Five-year outcomes of a randomized trial of treatments for varicose veins. N Engl J Med. 2019;381(10):912-922.

Morrison N, Kolluri R, Vasquez M, et al. Comparison of cyanoacrylate closure and radiofrequency ablation for the treatment of incompetent great saphenous veins: 36-Month outcomes of the VeClose randomized controlled trial. Phlebology. 2019;34(6):380-390.

ECRI Institute. Varithena Injectable Foam (Boston Scientific Corp.) for treating varicose veins. ECRI; 2020 Dec 11.

ECRI. VenaSeal Closure System (Medtronic plc.) for embolizing varicose veins. ECRI; 2021 Feb 4.

Hayes, Inc. Hayes Health Technology Assessment. Cyanoacrylate embolization (VenaSeal Closure System) for the treatment of varicose veins. December 2020. Updated December 2021.

Hayes, Inc. Hayes Health Technology Brief. Polidocanol endovenous microfoam (Varithena) 1% for treatment of varicose veins. May 2016. Updated December 2020.

Masuda E, Ozsvath K, Vossler J, et al. The 2020 appropriate use criteria for chronic lower extremity venous disease of the American Venous Forum, the Society for Vascular Surgery, the American Vein and Lymphatic Society, and the Society of Interventional Radiology. J Vasc Surg Venous Lymphat Disord. 2020 Jul;8(4):505-525.e4

Whing J, Nandhra S, Nesbitt C, Stansby G. Interventions for great saphenous vein incompetence. Cochrane Database Syst Rev. 2021 Aug 11;8(8):CD005624.

Ho VT, Adkar SS, Harris EJ. Systematic review and meta-analysis of management of incompetent perforators in patients with chronic venous insufficiency. J Vasc Surg Venous Lymphat Disord. Feb 22 2022

Novitas Solutions. Treatment of Chronic Venous Insufficiency of the Lower Extremities L34924/A55229

This policy will be revised as necessary and reviewed no less than annually.

Devised: 6/95

Revised: 10/97, 4/98, 12/99, 2/03(define criteria for each intervention), 9/03 add procedure, exclusion, coding, references, 6/04 (criteria and coverage change); 7/05 coding; 7/06 (coding/indications); 03/07; 3/10 (coding); 3/11(criteria, exclusion added); 12/12 (criteria), 12/14(added exclusion); 5/16 (removed exclusion); 5/18; 3/20 (Program exception note)

Reviewed: 3/08, 3/09, 3/12, 1/14, 1/16, 4/17, 3/19, 3/21, 3/22, 3/23, 3/24

CMS UM Oversight Committee Approval: 12/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

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