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Medicare Advantage Policy Manual

Varicose Vein Treatment

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual but they may also be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Varicose veins are caused by venous insufficiency as a result of valve reflux (incompetence), which results in dilated, tortuous, superficial vessels that protrude from the skin of the lower extremities. Varicose veins may be treated by sclerotherapy or surgical ligation when conservative measures (e.g., exercise, periodic leg elevation, weight loss, compressive therapy and avoidance of prolonged immobility) are unsuccessful.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: The Medicare references in this policy represent the guidance available at publication; please see the Medicare Coverage Database for the latest guidance. This policy includes links to external webpages that are not maintained by the health plan.

IMPORTANT NOTES:

- Procedures are subject to different criteria sets within the LCD itself. Use the table below for assistance in identifying the correct criteria set(s).
- When measurements are required, Noridian has this noted within the LCD. If not listed for a given service, then measurements are not required for coverage determinations.

CMS Coverage Manuals

None

National Coverage Determinations (NCDs)

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

Treatment of Varicose Veins of the Lower Extremities (LCD L34209) (Companion article A57706, see "Associated Documents" in the LCD). A57706 provides both procedural and diagnosis coding guidance.

Links to prior versions can be found at the bottom of the LCD.

Procedure(s):	CPT and/or HCPCS Code(s)	Criteria Section
Foam Sclerotherapy	36465, 36466	Criteria A & C
Treatment of telangiectasias (spider veins)	36468	Criteria C
Liquid Sclerotherapy	36470, 36471	Criteria A & C
Endovenous Mechanochemical Ablation (MOCA)	36473, 36474	Criteria A & C
Endovenous Radiofrequency Ablation [ERFA]	36475, 36476	Criteria A, B, & C
Endovenous Laser Ablation (EVLA)	36478, 36479	Criteria A, B, & C

Endovenous Chemical Adhesive (e.g., cyanoacrylate)	36482, 36483	Criteria A & C
Ligation, Division, and/or Stripping	37700, 37718, 37722, 37735, 37780, 37785	Criteria A & C
Subfascial Endoscopic Perforator Surgery (SEPS)	37760, 37761	Criteria A & C
Ambulatory Phlebectomy (Stab or Hook Phlebectomy)	37765, 37766	Criteria A & C
Transilluminated Powered Phlebectomy (TIPP; e.g., TRIVEX™)	37799	Criteria A & C
Treatment of varicose veins other than those in the lower extremities	Same as above	Billing and Coding: Treatment of Varicose Veins of the Lower Extremities (A57706)
		According to Article A57706, CPT codes 36465, 36466, 36470, 36471,36473, 36474, 36475, 36476, 36478, 36479, 36482, 36483, 37700, 37718, 37722, 37735, 37760, 37761, 37765, 37766, 37780 and 37785 all have a limited number of ICD-10-CM codes that support medical necessity. The Article adds that the "use of any ICD-10-CM code not listed in the "ICD-10-CM Codes That Support Medical Necessity" section of this LCD will be denied."

POLICY GUIDELINES

Varicose veins are caused by venous insufficiency as a result of valve reflux (incompetence). Venous incompetence in the lower extremity is a common clinical problem, and basic understanding of venous anatomy and pathophysiologic mechanisms of venous reflux is important for selecting the most appropriate treatment for an individual.

The venous system can be divided into three major components: the superficial venous system, the deep venous system, and the perforating veins.

- The superficial venous system has two parts: the thin-walled collecting veins and the thick-walled truncal veins (e.g., great and small saphenous veins, also known as greater or long and lesser or short saphenous veins, respectively).
- The veins of the deep venous system include the plantar vein (foot), the paired peroneal and anterior and posterior tibial veins (leg), and the popliteal and femoral veins (thigh), as well as venous sinusoids in muscles (e.g., soleal and gastrocnemius).
- Perforators connect the superficial and deep venous systems and play a role in balancing blood-flow during calf muscle contraction (e.g., Hunter and Dodd [mid- and distal thigh], Boyd [knee level] and Cockett [calf region).

Spider veins (telangiectasias) are dilated capillary veins close to the skin.

Varicose veins are generally associated with the lower extremities, but can also occur in other areas of the body as well.

REQUIRED DOCUMENTATION

The information below <u>must</u> be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Description of the planned treatment, including the location of the target areas and technique to be used (e.g., sclerotherapy, ligation, endoluminal radiofrequency ablation (ERFA), laser ablation, etc.)
- A history and physical examination supporting the diagnosis of symptomatic varicose veins, including symptoms experienced
- Documentation of the failure of an adequate (at least 3 months) trial of conservative management.
- For ERFA or laser ablation:
 - Presence or absence of any of the following conditions:
 - Aneurysm,
 - Thrombosis or vein tortuosity that would impair catheter advancement
 - Significant peripheral arterial diseases
 - Vein diameter
- Documentation of the performance of appropriate tests, if medically necessary, to confirm the pathology of the vascular anatomy.

REGULATORY STATUS

The following devices have received specific U.S. Food and Drug Administration (FDA) marketing clearance for the endovenous treatment of superficial vein reflux:

DEVICE	MANUFACTURER	FDA APPROVAL
The VenaSeal™ Closure System	Medtronic	2015
Steam Vein Sclerosis System (SVS™, VenoSteam™)	CermaVEIN, France	None
ClariVein® Infusion Catheter Predicate devices include the Trellis® Infusion System (K013635) and the Slip- Cath® Infusion Catheter (K882796).	Vascular Insights	2008
Polidocanol is an injectable sclerosing a varicose veins	gent that may be used for intravenous	s treatment of
Varithena® (formerly Varisolve®)	Biocompatibles, Inc, a BTG group company	2013
Asclera®	Merz North America, Inc.	2010
A modified Erbe Erbokryo® cryosurgical unit	Erbe USA	2005
Trivex system	Smith & Nephew	2003
Diomed 810 nm surgical laser and EVLT™ (endovenous laser therapy) procedure kit	Diomed, Inc.	2002
VNUS® Closure™ system (a radiofrequency device)	VNUS Medical Technologies, Inc.	1999
VNUS RFS and RFSFlex devices	VNUS Medical Technologies, Inc.	2005
A modified VNUS® ClosureFAST™ Intravascular Catheter	VNUS Medical Technologies, Inc.	2008
Microwave Intracavitary Coagulation System	Shanghai Medical Electronics, China	None

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Cosmetic and Reconstructive Procedures, Surgery, Policy No. M-12

REFERENCES

- 1. Noridian Billing and Coding: Sclerosing of Varicose VeinsA53084
- 2. Noridian Article for Response to Comments: Treatment of Varicose Veins of Lower Extremities A54715

CODING

NOTES:

- Prior to January 1, 2017, there is no specific CPT code for mechanochemical treatment devices (e.g., the ClariVein® device), which should be reported with an unlisted procedure code (such as 36299 as recommended by Noridian or 37799). For services rendered on or after January 1, 2017, CPT codes 36473 for the initial vein treated and 36474 for subsequent veins should be used. Per CPT and Noridian guidelines, it is inappropriate to use codes 37241-37244 or 37475-37479 to report this procedure.^[1]
- Varithena® is not separately reimbursable using any CPT or HCPCS code.
- There is no specific CPT code for transilluminated powered phlebectomy (e.g., Trivex), but according to the Noridian Article, unlisted CPT code 37799 should be used to report for this procedure.

Codes	Number	Description
CPT	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 (eg, great saphenous vein, accessory saphenous vein)
	36466	;multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg
	36468	Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk
	36470	Injection of sclerosing solution; single vein
	36471	Injection of sclerosing solution; multiple veins, same leg
	36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
	36474	;subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

Codes	Number	Description
	36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
	36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
	36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
	36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
	36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
	36483	;subsequent vein(s) treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure)
	37700	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
	37718	Ligation, division, and stripping, short saphenous vein (for bilateral procedure, use modifier 50)
	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 or 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 veins, subfascial, radical (Linton type) including skin graft, when performed, open, 1 leg
	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

Codes	Number	Description
	37766	Stab phlebectomy of varicose veins, one extremity; more than 20 incisions
	37780	Ligation and division of short saphenous vein at saphenopopliteal 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 studies
	0524T	Endovenous 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
HCPCS	J3490	Unclassified drugs Note: If used for Varithena®, see coding note above
	S2202	Echosclerotherapy (Not recognized by Medicare for payment)