# **Medicare Medical Policy**

# **Varicose Veins**

**MEDICARE MEDICAL POLICY NUMBER: 187** 

Effective Date: 1/1/2025	MEDICARE COVERAGE CRITERIA	2
Last Review Date: 12/2024	POLICY CROSS REFERENCES	
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**INSTRUCTIONS FOR USE:** Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

**SCOPE:** Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

# PRODUCT AND BENEFIT APPLICATION

# **MEDICARE COVERAGE CRITERIA**

**IMPORTANT NOTE:** More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Varicose Vein Treatment –	Local Coverage Determination (LCD): Treatment of Varicose Veins
Lower Extremities	of the Lower Extremities ( <u>L34010</u> )
	<b>NOTE:</b> In addition to the criteria detailed in the above LCD, the companion local coverage article <u>LCA A57707</u> provides a list of medically necessary diagnosis codes to support covered procedures. This LCA states "these are the only ICD-10-CM codes that support medically necessity." Thus, in addition to meeting the coverage criteria in the LCD, a medically necessary diagnosis code must also be submitted and supported by the clinical documentation.

#### **NOTES:**

- Varicose vein procedures are subject to different criteria sets within the above LCD. The
  rows below were developed to provide assistance in identifying the relevant criteria set(s)
  for different procedures.
- See "Policy Guidelines" below for more information, as well as information regarding measurement requirements.

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PROCEDURE	CPT CODE(S)	CRITERIA
Ligation and Excision	37700, 37718, 37722, 37735, 37780,	Criteria A & C
(Stripping)	37785	
Subfascial endoscopic	37760, 37761	Criteria A & C
perforator surgery (SEPS)		
Ambulatory Phlebectomy (stab	37765, 37766, 37799 (latter is used for	Criteria A & C
or hook) and Transilluminated	either TPPS <i>or</i> if less than 10 stab	
Powered Phlebectomy (TPPS;	incisions)	
e.g., TriVex System)		

Endovenous mechanochemical ablation (MOCA; ClariVein® Infusion Catheter)	36473, 36474	Criteria A & C
Sclerotherapy (foam [i.e., Varithena™] or liquid [i.e., Asclera®])	36465, 36466, 36470, 36471	Criteria A & C
Endovenous ablation therapy (i.e., radiofrequency [ERFA], laser [EVLA], or chemical [e.g., cyanoacrylate])	36475, 36476, 36478, 36479, 36482, 36483	Criteria A, B, & C  Note criterion B also includes criterion A.
Treatment of spider veins (telangiectasias)	36468	Introductory paragraph and Criterion C
Varicose Vein Treatment – All Other Indications	Local Coverage Article (LCA): Billing and Coding: Treatment of Varicose Veins of the Lower Extremities (A57707) (This LCA provides a list of the only ICD-10 codes that support medical necessity for varicose vein treatment codes and states the use of any ICD-10 code not on the list are considered to be not medically reasonable or necessary.)	

**Medicare Coverage Criteria:** "MA organizations may create publicly accessible internal coverage criteria... when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." (§ 422.101(b)(6) – see Policy Guidelines below)

- **Medicare Coverage Manuals:** Medicare does not have criteria for varicose vein treatment in a coverage manual.
- National Coverage Determination (NCD): Medicare does not have an NCD for varicose vein treatment
- Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA): As of the
  most recent policy review, while most Medicare Administrative Contractors (MACs) have LCDs
  for varicose vein treatment, no LCD exists for some techniques used for varicose vein
  treatment, such as endovenous catheter directed chemical ablation with balloon isolation
  (e.g., KAVS procedure; 0524T).
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there is no Medicare coverage criteria available for the KAVS procedure (0524T).
- **NOTE:** The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].

Techniques Not Otherwise	Company medical policy for Varicose Veins
<ul> <li>Endovenous catheter directed chemical ablation with balloon isolation (e.g., KAVS procedure; 0524T)</li> </ul>	I. This service is considered <b>not medically necessary</b> for Medicare based on the Company medical policy. <u>See Policy Guidelines below</u>

**IMPORTANT NOTICE:** While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)

# **POLICY CROSS REFERENCES**

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

# **POLICY GUIDELINES**

#### **VEIN DIAMETER MEASUREMENTS**

Some of the procedures addressed in this policy require vein diameter measurements in order to meet coverage requirements. When measurements are required, Noridian has this specifically noted within the LCD - if measurements are not listed for a given service within the LCD, then measurements would not be required to determine medical necessity.

#### CRITERIA AND CODE DECIPHERING FOR LCD L34010

**Prior to** 12/1/2019, Noridian included CPT codes within the LCD L34010 to direct readers to applicable criteria for each relevant CPT code.

A. Indications for surgical treatment (CPT codes: 37700, 37718, 37722, 37735, 37760, 37761, 37765, 37766, 37780, 37785) and sclerotherapy (CPT codes: 36470, 36471):

- 1. A 3-month trial of conservative therapy such as exercise, periodic leg elevation, weight loss, compressive therapy, and avoidance of prolonged immobility where appropriat
- 2. The patient is symptomatic and has one, or more, of the following:
- a. Pain or burning in the extremity severe enough to impair mobility
- b. Recurrent episodes of superficial phlebitis
- c. Non-healing skin ulceration
- d. Bleeding from a varicosity
- e. Stasis dermatitis
- f. Refractory dependent edema

B. Indications for ERFA or laser ablation (CPT codes 36465, 36466, 36475, 36476, 36478, 36479, 36482, 36483):

With the **12/1/2019** update of the LCD, all billing and coding information was removed. This meant all CPT codes were removed from the LCD, including codes used for informational purposes when deciphering criteria. However, the criteria language did not change and communication from Noridian confirms their coverage *intent* remains the same. Therefore, the code instruction in the criteria table above are based on this historical LCD layout with CPT codes.

#### **ULTRASOUND GUIDANCE AND ECHOSCLEROTHERAPY**

According to L34010, "2. Intra-operative ultrasound guidance is not separately payable with ERFA, laser ablation, and sclerotherapy." While the LCD acknowledges that clinical "outcomes may be improved and complication rates may be minimized when ultrasound guidance is used," the CPT code descriptions for radiofrequency (ERFA) and laser ablation include the intraoperative ultrasound service in the valuation. For sclerotherapy, the LCD adds "intra-operative ultrasound guidance techniques have not been shown to increase the effectiveness or safety of sclerotherapy for varicose veins." Thus, separate reporting of intra-operative ultrasound is inappropriate with any of these procedures and will not be considered for reimbursement.

# ENDOVENOUS CATHETER DIRECTED CHEMICAL ABLATION WITH BALLOON ISOLATION (KAVS PROCEDURE)

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. (§ 422.101(c)(1))

#### In addition:

"MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." (§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

The KAVS [catheter-assisted vein sclerotherapy] procedure involves an intravascular catheter with a balloon to temporarily block blood flow to the segment of vein targeted for sclerotherapy.

CPT code 0524T, which is used to report this procedure, was previously included in the Noridian local coverage article (LCA) for *Additional Information Required for Coverage and Pricing for Category III CPT® Codes* (A55681). It was listed as a Group 1 code, indicating Noridian had "not received sufficient information to make coverage and pricing determinations" and thus was non-covered. When this LCA was retired in June 2020, no replacement Medicare policy was created to address this technique, nor was it added to the existing LCD/LCA for varicose vein treatments.

Since there are not fully established coverage criteria for some techniques for varicose vein treatment (e.g., KAVS) available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the <u>Medicare Coverage Criteria</u> table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

## REGULATORY STATUS

#### **U.S. FOOD & DRUG ADMINISTRATION (FDA)**

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

# **BILLING GUIDELINES AND CODING**

#### **GENERAL**

See associated local coverage articles (LCAs) for related billing and coding guidance:

• LCA: Billing and Coding: Treatment of Varicose Veins of the Lower Extremities (A57707)

## Stab Phlebectomy

While CPT code 37765 is used to report stab phlebectomy of 10-20 incisions and CPT code 37766 is used to report for more than 20 incisions, there is no specific CPT code to report stab phlebectomy with less than 10 incisions. According to CPT instructions, this procedure would be reported with CPT code 37799 (Unlisted procedure, vascular surgery).

### **ECHOSCLEROTHERAPY (HCPCS CODE S2202)**

Ultrasound guided sclerotherapy is also known as echosclerotherapy.

Like all S-codes, the *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by the Centers for Medicare and Medicaid Services (CMS)<sup>1</sup>, indicates HCPCS code S2202 has been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." In addition, HCPCS code S2202 is not recognized as a valid code for claim submission as indicated in the relevant Company Coding Policy (HCPCS S-Codes and H-Codes, 22.0). Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered. Note that according to the above LCD, separate payment for intraoperative ultrasound guidance is not made with sclerotherapy codes.

CODE	ES*	
СРТ	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
	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	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; 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	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	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	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; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
	37500	Vascular endoscopy, surgical, with ligation of 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
	27725	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 perforator 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, 1 extremity; 10-20 stab incisions
	37766	Stab phlebectomy of varicose veins, 1 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), 1 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
HCPCS	J3490	Unclassified drugs
	S2202	Echosclerotherapy (CMS-assigned Status "I" code - This code is not valid for Medicare purposes.)

#### \*Coding Notes:

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does not make a procedure medically reasonable or necessary or a covered benefit by Medicare. (Medicare Claims Processing Manual, Chapter 23 Fee Schedule Administration and Coding Requirements, §30 Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior authorization is recommended.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy, Reimbursement Policy, Pharmacy</u> Policy and Provider Information website for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling
  edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and
  Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website
  for coding guidelines and applicable code combinations.

### REFERENCES

 Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: <a href="https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files">https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files</a>

# **POLICY REVISION HISTORY**

DATE	REVISION SUMMARY
12/2022	Annual review (converted to new format 2/2023)
3/2024	Annual review; changed criteria for the KAVS procedure (0524T) to use Company policy
	criteria and added code guidance to the criteria table
1/2025	Annual review, no criteria change