Coverage Alert

Varithena® (polidocanol injectable foam) 1%

2024-2025 VARITHENA PAYER COVERAGE UPDATE

This alert addresses multiple commercial payer varicose vein policy updates including, Cigna Healthcare, Culinary Health Fund™, Excellus BlueCross Blue Shield, Independence Blue Cross (IBX), Palmetto GBA™, United Healthcare Commercial and Individual Exchange and Affiliates (including UMR) and Community Plan Medical.

Click on the image below to access the current UHC policy.


United Healthcare

UnitedHealthcare® Commercial and Individual Exchange
Medical Policy

Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins

Policy Number: 2024T0447NN
Effective Date: July 1, 2024

Instructions for Use

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Related Commercial/Individual Exchange Policies
- Cosmetic and Reconstructive Procedures
- Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome
- Outpatient Surgical Procedures – Site of Service

Community Plan Policy
- Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins

Medicare Advantage Coverage Summary
- Varicose Veins Treatment and Other Vein Embolization Procedures

Application

UnitedHealthcare Commercial
This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange
This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

Below is a description of three of the most recent updates, UHC, Cigna and Independence BC

United Healthcare

United Healthcare is one of the largest Commercial Insurance Providers. Approximately 23 million people in the U.S. rely on UnitedHealthcare Employer & Individual insurance through insured and self-funded plans.

United Healthcare updated its Commercial Policy for Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins:

- UHC removed “Endovenous low-nitrogen foam Sclerotherapy” (Varithena) from their list of unproven and not medically necessary treatments.
- UHC Added a “Sclerotherapy” section stating “Refer to the Applicable codes section for Sclerotherapy (i.e., liquid, foam, ultrasound-guided, endovenous chemical ablation, endovenous microfoam).

Link to the current policy: Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins – Commercial and Individual Exchange Medical Policy (uhcprovider.com)

Link to Community Plan Policies*: Medical and Drug Policies for Community Plan | UHCprovider.com

What are the Criteria*?

- Codes applicable to Sclerotherapy sections 36465, 36466, 36470, 36471
- More than 3 sessions per leg within a year is considered cosmetic
- A session is defined as one date of service in which one of the services described by these codes is used
- A year is defined as a rolling 12 months (365) days
- Individual must have one of the following Functional or Physical Impairments:
  - Skin ulceration; or o Documented episode(s) of frank bleeding of the Varicose Vein due to erosion of/or trauma to the skin
  - or Documented Superficial Thrombophlebitis; or o Documented Venous Stasis Dermatitis causing Functional or Physical Impairment
  - or Moderate to Severe Pain causing Functional or Physical Impairment
- Description of physiologic function being improved or restored
- Venous size:
  - The GSV must be 3.0. mm or greater when measured at the proximal thigh immediately below the saphenofemoral junction via Duplex Ultrasonography
  - The SSV* or Accessory Veins must measure 3.0 mm or greater in diameter immediately below the appropriate junction via Duplex Ultrasonography

Boston Scientific

* Treatment of the SSV is off-label for Varithena. Please see important information on pages 5-6

- Duplex ultrasound study performed in the standing or reverse Trendelenburg position, shows duration of reflux that meets the following parameters:
  - Greater than or equal to 500 milliseconds (ms) for the GSV, SSV*, or principal tributaries
  - Acceptable - Duplex Ultrasound readings described this as moderate to severe reflux

* Some states have Community Health policies specific to their states and criteria may (but does not always) vary. Use the link above to find your state policy. State-specific policies include, IN, KY, LA, MS, NJ, NM, NC, OH, PA and TN.
* *Varithena™ is not indicated by the FDA for treating Perforator Veins or Small Saphenous Veins (SSV*).

**CPT codes 36465, 36466, 36470, and 36471 are covered for sclerotherapy up to 3 sessions per leg within a year.

- More than 3 sessions per leg within a year is considered cosmetic; does not improve a functional, physical, or physiological impairment. Cosmetic sclerotherapy is excluded. (2019 Certificate of Coverage Amendment).
- A session is defined as one date of service in which sclerotherapy (36465, 36466, 36470, 36471) is performed.
- A year is defined as a rolling 12 months (365 days).

CPT Code	Description
0744T	Insertion of bioprosthetic valve, open, femoral vein, including duplex ultrasound imaging guidance, when performed, including autogenous or nonautogenous patch graft (e.g., polyester, ePTFE, bovine pericardium), when performed
**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 (e.g., 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 (e.g., great saphenous vein, accessory saphenous vein), same leg
*36468	Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk
**36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)
**36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg

Click on the image above for on online version of the current UHC policy.

Why is this important?

United Healthcare's update allows patients with Chronic Venous Insufficiency access to Varithena, providing physicians with another treatment option.

Additional UHC affiliates completing the same update include, Oxford, UMR, UHC of CA HMO, UHC of OK, UHC of OR,

Please contact your Territory Sales Manager, or Field Reimbursement Manager for questions about this Alert.

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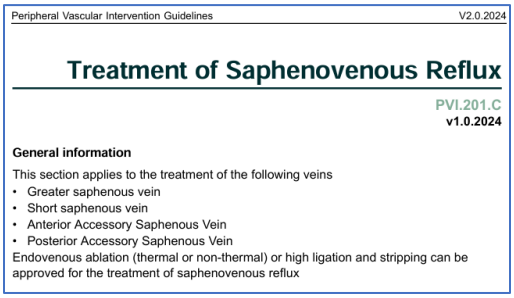
Cigna Healthcare

Cigna Healthcare is one of the top five medical commercial insurers by members' lives. Approximately 13 million people in the U.S. rely on UnitedHealthcare Employer & Individual medical insurance through insured and self-funded plans.

Cigna retired its Varicose Veins Treatment Coverage Policy #0234 and is now using the cobranded Cigna/EviCore "Treatment of Saphenous Reflux" Clinical Guidelines to define its coverage.


Peripheral Vascular Intervention Guidelines V2.0.2024

Treatment of Saphenovenous Reflux

PVI.201.C
v1.0.2024

General information

This section applies to the treatment of the following veins
- Greater saphenous vein
- Short saphenous vein
- Anterior Accessory Saphenous Vein
- Posterior Accessory Saphenous Vein

Endovenous ablation (thermal or non-thermal) or high ligation and stripping can be approved for the treatment of saphenovenous reflux

The following documents detail Cigna's policy update.

1. Cigna Retired Coverage Policy #0234 can be found online here. This policy also states, "For dates of service 11/1/ and after, see policy: Evicore Cigna Commercial Membership I EviCore bv Evernorth".
2. EviCcore Peripheral Vascular Intervention Clinical Guidelines can be found online here. This is a large document with multiple policies. The policies specific to this change include:
    a. Treatment of Saphenovenous Reflux PVI.201.C, v1.0.2024 (pg 33).
    b. General Information for Venous Intervention Requests PVI.200A, v1.0.2024 (pg 31).

When did this happen?

Cigna retired its Varicose Veins Treatment Clinical Policy #0234 effective 11/2/2024

What was Varithena's coverage under the previous/now retired policy?

- Primary coverage only for High-risk patients
    - Patients with ulcers
    - Patients with recurrent bleeding
    - Patients with a history of a significant episode of bleeding
- Secondary/Adjunctive coverage for Low-risk patients (all others that do not qualify for high-risk)
    - Patients could be treated with Varithena as a secondary/ Adjunctive procedure after reflux proximal was ablated with RF/Laser, ligation, or excision.

What is the new coverage in the Cigna/EviCore Clinical Evidence Guidelines

The Evicore guidelines allow for primary treatment with non-compounded foam (Varithena) represented by CPT codes 36465 or 36466 when the "Treatment of Saphenous Reflux" guideline criteria are met. Thus, Varithena moved from a secondary/adjunctive procedure to a primary treatment procedure when clinical guideline criteria are met!

Why is this important?

Cigna's update to the use of EviCore guidelines provides patient access to Varithena as a primary, proximal vein treatment (following conservative therapy) for the GSV, SSV*, AASV and PASV when policy criteria are met.

* Treatment of the SSV is off-label for Varithena. Please see important information on pages 5-6

Independence Blue Cross (IBX)

IBX is a regional BCBS organization with approximately 1.2 million commercial lives primarily in PA.

IBX is updating its Treatment of Varicose Veins of the Lower Extremities and Perforator Vein Incompetence policy, Policy # 11.02.01t.

When did this happen?

- This IBX updated policy is effective 1/13/2025

What was Varithena's coverage under the previous/now retired policy?

- Patients could be treated with Varithena as a secondary/ Adjunctive procedure after reflux proximal was ablated with RF/Laser, ligation, or excision.

What is the new coverage in the update policy?

- The updated policy allows primary treatment with microfoam sclerotherapy for the GSV, SSV*, and Accessory Saphenous Veins.
- CPT codes 36465 or 36466 are included in the “Medically Necessary” coding section.

Why is this important?

IBX’s update provides patient access to Varithena as a primary, proximal vein treatment (following conservative therapy) for the GSV, SSV*, and Accessory Saphenous Veins.

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IMPORTANT INFORMATION

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies.

This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice.

Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered.

It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters.

Boston Scientific does not promote the use of its products outside their FDA-approved label.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements.

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Coverage Alert

VARITHENA BRIEF SUMMARY: 1 INDICATIONS AND USAGE VARITHENA (polidocanol injectable foam) is indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the great saphenous vein (GSV) system above and below the knee. VARITHENA improves the symptoms of superficial venous incompetence and the appearance of visible varicosities. **2 DOSAGE AND ADMINISTRATION** For intravenous use only. VARITHENA is intended for intravenous injection using ultrasound guidance, administered via a single cannula into the lumen of the target incompetent trunk veins or by direct injection into varicosities. Use up to 5 mL per injection and no more than 15 mL per session Physicians administering VARITHENA must be experienced with venous procedures and be trained in the administration of VARITHENA. Activate VARITHENA using the VARITHENA oxygen canister and polidocanol canister (see Instructions for Use). Once a VARITHENA transfer unit is in place, foam can be generated and transferred to a syringe. Discard the syringe contents if there are any visible bubbles. Administer the injectable foam within 75 seconds of extraction from the canister to maintain injectable foam properties. Use a new sterile syringe after each injection. Use a new VARITHENA transfer unit for each treatment session. Local anesthetic may be administered prior to cannula insertion but neither tumescent anesthesia nor patient sedation is required. Cannulate the vein to be treated using ultrasound guidance to confirm venous access. Inject freshly generated VARITHENA injectable foam slowly (approximately 1 mL/second in the GSV and 0.5 mL/second in accessory veins or varicosities) while monitoring using ultrasound. Confirm venospasm of the treated vein using ultrasound. When treating the proximal GSV, stop the injection when VARITHENA is 3-5 cm distal to the saphenofemoral junction (SFJ). Apply compression bandaging and stockings and have the patient walk for at least 10 minutes, while being monitored. Maintain compression for 2 weeks after treatment. Repeat treatment may be necessary if the size and extent of the veins to be treated require more than 15 mL of VARITHENA. Separate treatment sessions by a minimum of 5 days. Retained coagulum may be removed by aspiration (microthrombectomy) to improve comfort and reduce skin staining. **3 DOSAGE FORMS AND STRENGTHS** VARITHENA is available in the following presentations: • 180 mg/18 mL (10 mg/mL) • 77.5 mg/7.75 mL (10 mg/mL) Once activated, VARITHENA is a white, injectable foam delivering a 1% polidocanol solution. Each mL of VARITHENA injectable foam contains 1.3 mg of polidocanol **4 CONTRAINDICATIONS** The use of VARITHENA is contraindicated in patients with: • known allergy to polidocanol [see Warnings and Precautions (5.1)] • acute thromboembolic disease **5 WARNINGS AND PRECAUTIONS 5.1 Anaphylaxis** Severe allergic reactions have been reported following administration of liquid polidocanol, including anaphylactic reactions, some of them fatal. Observe patients for at least 10 minutes following injection and be prepared to treat anaphylaxis appropriately. **5.2 Tissue Ischemia and Necrosis** Intra-arterial injection or extravasation of polidocanol can cause severe necrosis, ischemia or gangrene. Patients with underlying arterial disease, such as marked peripheral arteriosclerosis or thromboangiitis obliterans (Buerger's Disease) may be at increased risk for tissue ischemia. If intra-arterial injection of polidocanol occurs, consult a vascular surgeon immediately. **5.3 Venous Thrombosis** VARITHENA can cause venous thrombosis [see Adverse Reactions (6)]. Follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent (within 3 months) major surgery, prolonged hospitalization, or pregnancy are at increased risk for developing thrombosis. **6 ADVERSE REACTIONS 6.1 Clinical Trials Experience** Because clinical trials are conducted under controlled but widely varying conditions, adverse reaction rates observed in clinical trials of VARITHENA cannot be directly compared to rates in the clinical trials of other drugs or procedures and may not reflect the rates observed in practice. A total of 1333 patients with GSVI in 12 clinical trials were evaluated for safety when treated with VARITHENA at dose concentrations of 0.125%, 0.5%, 1.0%, or 2.0%, including 437 patients treated with VARITHENA in placebo-controlled clinical trials. Adverse reactions occurring in 3% more patients receiving VARITHENA 1% than receiving placebo are shown in Table 1. Table 1: Treatment-emergent adverse reactions (3% more on VARITHENA 1% than on placebo) through Week 8 (n=588) **Adverse Reaction:** *Placebo (N=151)*, Varithena 1.0% (N=149). Pain in extremity: *14 (9.3)*, 25 (16.8), Infusion site thrombosis[a]: *0*, 24 (16.1), Contusion/injection site hematoma: *9 (6.0)*, 23 (15.4), Limb discomfort: *5 (3.3)*, 18 (12.1), Tenderness/injection site pain: *5 (3.3)*, 16 (10.7), Venous thrombosis limb[b]: *0*, 12 (8.1), Thrombophlebitis superficial: *2 (1.3)*, 8 (5.4), Deep vein thrombosis: *0*, 7 (4.7). [a] Retained coagulum. [b] Common femoral vein thrombus extension (non-occlusive thrombi starting in the superficial vein and extending into the common femoral vein). In VARITHENA-treated patients, 80% of pain events in the treated extremity resolved within 1 week. Proximal symptomatic venous thrombi occurred in <1% of patients treated with VARITHENA. Approximately half of patients with thrombi received treatment with anticoagulants. Since VARITHENA induces thrombosis in the treated superficial veins, D-dimer is commonly elevated post-treatment and is not useful diagnostically to assess patients for venous thrombus following treatment with VARITHENA. Neurologic adverse events (cerebrovascular accident, migraines) have been reported in patients following administration of physician compounded foam sclerosants. None of the 1333 patients in the VARITHENA trials experienced clinically important neurological or visual adverse events suggestive of cerebral gas embolism. The incidence of neurologic and visual adverse events within 1 day of treatment in the placebo-controlled studies was 2.7% in the pooled VARITHENA group and 4.0% in the placebo groups. Skin discoloration adverse events were reported in 1.1% of the pooled VARITHENA group and 0.7% of the placebo group in the placebo-controlled studies. **7 DRUG INTERACTIONS** No specific drug interaction studies have been performed. There are no known drug interactions with VARITHENA. **8 USE IN SPECIFIC POPULATIONS 8.1 Pregnancy** Risk Summary Few published case reports with use of polidocanol-containing products, including VARITHENA, in pregnant women have not identified any drug-associated risk for major birth defects, miscarriage, or adverse maternal or fetal outcomes. Although no risks have been identified, there is minimal benefit in treating lower extremity varicosities during pregnancy and lower extremity varicosities that develop during pregnancy as they may spontaneously regress postpartum. In animal reproduction studies, no adverse developmental effects were observed with intravenous administration of polidocanol to pregnant rats and rabbits during organogenesis at dose levels up to approximately 13.5 and 12 times, respectively, the proposed maximum human dose of 15 mL of 1% VARITHENA based on body surface area (see Data). The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively. **Data** Animal Data Developmental reproductive toxicity testing was performed in rats and rabbits using intravenous administration of polidocanol solution. In rabbits, dose levels up to and including 10 mg/kg/day (approximately 12 times the proposed maximum human dose of 15 mL of 1% VARITHENA based on body surface area) did not produce any indication of adverse effects on embryo-fetal mortality, fetal weight, or the incidences of fetal abnormalities and variants. In rats administered 27 mg/kg/day of polidocanol solution (approximately 13.5 times the human dose based on body surface area), there were no adverse effects on pregnancy performance or fetal development. In a peri-natal and post-natal study in rats, dose levels of polidocanol up to 9 mg/kg/day (approximately 4.5 times the human dose based on body surface area) were without effects on the development of the conceptus and offspring, and at a dose level of 27 mg/kg/day of polidocanol solution (approximately 13.5 times the human dose based on body surface area), effects were confined to an equivocal reduction in body weights of first-generation males, and an associated equivocal delay in the age of preputial separation. **8.2 Lactation** Risk Summary There are no data on the presence of polidocanol in human milk, the effects on the breastfed infant, or the effects on milk production. A lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk up to 8 hours after VARITHENA administration in order to minimize exposure to a breastfed infant. **8.4 Pediatric Use** Safety and effectiveness in pediatric patients have not been established. **8.5 Geriatric Use** Of the 1333 subjects in clinical studies treated with VARITHENA, 9.1% (n=121) were ≥65 years of age. No clinically important differences in safety or efficacy were observed between older and younger patients in all studies. **10 OVERDOSAGE** There are no known cases of overdosage with VARITHENA. In clinical studies, total volumes of up to 60 mL of VARITHENA per treatment session have been administered. RX Only PI**-726302-AB**

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