

2024 MEDICARE PHYSICIAN FEE SCHEDULE (PFS) FINAL RULE

This alert addresses the 2024 Final Rule update to CPT® coding and Medicare's final payment rates for Varithena ® and other vein ablation modalities.

HIGHLIGHTS OF THE 2024 PFS Final Rule

- The Medicare Physician Fee Schedule Final Rule includes a 3.37% reduction to the Conversion Factor, from \$33.89 to \$32.74, a portion of the formula determining physician payment rates.
- Medicare moved forward with the third year of the 4-year phase-in of the labor pricing update portion of the non-facility practice expense inputs, resulting in further reductions for some procedures.

COMPARISON OF MEDICARE 2024 PFS FINAL RULE NATIONAL UNADJUSTED FEE SCHEDULE RATES AND RVUS VS MEDICARE 2023 FINAL PFS NATIONAL UNADJUSTED FEE SCHEDULE RATES AND RVUS

Physician Fee Schedule (PFS) CY2024 Final Rule PMT Rates 2024 Final vs 2023 Final											
36465	Varithena: 1 vein	2.35	39.49	3.48	\$1,338	2.35	38.22	3.49	\$1,251	-\$87	-6.5%
36466	Varithena: >1 vein	3.00	42.63	4.49	\$1,445	3.00	40.36	4.45	\$1,322	-\$123	-8.5%
36470	Sclerotherapy: 1 vein	0.75	3.46	1.14	\$117	0.75	3.46	1.12	\$113	-\$4	-3.4%
36471	Sclerotherapy: >1 vein	1.50	5.98	2.23	\$203	1.50	5.99	2.23	\$196	-\$7	-3.2%
36473	ClariVein: 1st vein	3.50	36.63	5.29	\$1,241	3.50	35.64	5.32	\$1,167	-\$74	-6.0%
36474	ClariVein: Each add'l vein	1.75	7.71	2.63	\$261	1.75	7.47	2.60	\$245	-\$17	-6.4%
36475	RF: 1st vein	5.30	32.47	8.13	\$1,100	5.30	31.71	8.15	\$1,038	-\$62	-5.6%
36476	RF: Each add'l vein	2.65	8.51	3.92	\$288	2.65	8.35	3.90	\$273	-\$15	-5.2%
36478	Laser: 1st vein	5.30	29.47	8.12	\$999	5.30	28.96	8.15	\$948	-\$50	-5.0%
36479	Laser: Each add'l vein	2.65	8.98	3.96	\$304	2.65	8.98	3.98	\$294	-\$10	-3.4%
36482	Venaseal: 1st vein	3.50	50.38	5.22	\$1,707	3.50	49.27	5.26	\$1,613	-\$94	-5.5%
36483	Venaseal: Each add'l vein	1.75	4.07	2.59	\$138	1.75	4.09	2.59	\$134	-\$4	-2.9%
37765	Stab phleb Veins Extr 10-20	4.80	12.66	7.96	\$429	4.80	12.55	7.98	\$411	-\$18	-4.2%
37766	Stab phleb veins extr 20+	6.00	14.85	9.74	\$503	6.00	14.76	9.78	\$483	-\$20	-4.0%

SOURCES

CMS Final Rule Notices and Relative Value Files 2023: <u>CMS-1770-F | CMS</u>
Updated 2024 Final Physician Fee Schedule Relative Value File Released 11/02/2023: <u>CMS-1784-F | CMS</u>

Please see the next page and pages 2 & 3 for important information about this Reimbursement Alert.



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Please see next page 2 and page 3 for important indications, usage and safety information associated with this Reimbursement 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 placebocontrolled 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*: 0, 12 (8.1), Thrombophlebitis superficial: 2 (1.3), 8 (5.4), Deep vein thrombosis: 0, 7 (4.7). *Retained coagulum. *Common femoral vein thrombos 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 Varithena is a registered trademark of Boston Scientific Corporation or its affiliates. All trademarks are the property of their respective owners.



Peripheral Interventions 300 Boston Scientific Way Marlborough, MA 01752-1234

www.bostonscientific.com

Medical Professionals: PIReimbursement@bsci.com

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