02.01.54 Miscellaneous Treatments for Varicose Veins/Venous Insufficiency

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Related Policies:

- 10.01.02 Cosmetic and Reconstructive Services

Summary

Description

A variety of treatment modalities are available to treat varicose veins/venous insufficiency, including surgery, thermal ablation, mechanochemical ablation (MOCA), and cryotherapy. The application of each modality is influenced by the severity of the symptoms, type of vein, source of venous reflux, and the use of other (prior or concurrent) treatment.

Note: *Prior approval is required for certain treatment modalities related to the treatment of varicose veins/venous insufficiency refer to Wellmark Authorization Table to determine what treatment modalities*

have a prior approval requirement and the medical necessity clinical coverage criteria using InterQual® criteria.
This evidence review will address ultrasound guidance related to sclerotherapy and treatment modalities that are considered investigational.

Summary of Evidence

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cryoablation, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, morbid events, quality of life (QOL), and treatment-related morbidity. Results from a recent RCT of cryoablation have indicated that this therapy is inferior to conventional stripping. Studies showing a benefit on health outcomes are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive mechanochemical ablation (MOCA), the evidence includes 4 RCTs with 6 months to 2-year results that compared MOCA to thermal ablation, and 2 prospective cohorts with follow-up out to 8 years. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. MOCA is a combination of liquid sclerotherapy with mechanical abrasion. A potential advantage of this procedure compared with thermal ablation is that MOCA does not require tumescent anesthesia and may result in less pain during the procedure. Results to date have been mixed regarding a reduction in intraprocedural pain compared to thermal ablation procedures. Occlusion rates at 6 months to 2 years from RCTs indicate lower anatomic success rates compared to thermal ablation, but a difference in clinical outcomes at these early time points has not been observed. Experience with other endoluminal ablation procedures suggests that lower anatomic success in the short term is associated with recanalization and clinical recurrence between 2 to 5 years. The possibility of later clinical recurrence is supported by prospective cohort studies with 8-year follow-up following treatment with MOCA. However, there have been improvements in technique since the cohort studies began, and clinical progression is frequently observed with venous disease. Because of these limitations, longer follow-up of the more recently conducted RCTs is needed to establish the efficacy and durability of this procedure compared with the criterion standard of thermal ablation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency who receive coil embolization there is scant published literature addressing coil embolization for treatment of lower extremity veins (Van Dijk et al 1999 and Viani et al 2014). Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Currently, coil embolization is not an approach widely accepted by the practicing medical community for the treatment of varicose veins. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with varicose veins/venous insufficiency who received KAVS [catheter-assisted vein sclerotherapy] procedure, no comparative effectiveness evidence was identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to evaluate whether the use of ablative, chemical, and adhesive technologies to treat varicose veins/venous insufficiency arising from reflux in the saphenous, tributary, and perforator veins improves net health outcomes.

PRIOR APPROVAL

Prior approval is required for certain treatment modalities related to the treatment of varicose veins/venous insufficiency refer to Wellmark Authorization Table to determine what treatment modalities have a prior approval requirement and the medical necessity clinical coverage criteria using InterQual® criteria.

POLICY

Ultrasound Guidance Related to Sclerotherapy in the Treatment of Symptomatic Varicose Veins/Venous Insufficiency

Ultrasound or radiological guidance monitoring techniques are of no proven value when performed solely to guide the needle or introduce the sclerosant into the varicose veins and is considered **not medically necessary**.

Investigational

The following treatments for symptomatic varicose veins/venous insufficiency are considered **investigational.** The evidence is insufficient to determine this technology improves net health outcomes (this list may not be all-inclusive):

- Coil embolization
- Cryoablation (cryostripping)
- Endomechanical ablative approaches using rotating catheter (e.g., ClariVein Catheter) (e.g., mechanical occlusion chemically assisted ablation [MOCA], mechanic-chemical endovenous ablation [MCEA], mechanically enhanced endovenous chemical ablation [MEECA)
- Endovenous catheter directed chemical ablation with balloon isolation (e.g., KAVS procedure)
- VenoValve

ALL Category III codes will be considered **investigational** unless the code is explicitly addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy.

POLICY GUIDELINES

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many health care professionals across the country, and the service or procedure may not have proven clinical efficacy. Certain T codes may be addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy. But, unless there is explicit Policy criteria that specifically extends coverage to a particular Category III code, the code would generally be considered experimental, investigational, or unproven.

Coding

See the Codes table for details.

BACKGROUND

Venous Reflux/Venous Insufficiency

The venous system of the lower extremities consists of the superficial veins (this includes the great and small saphenous and accessory, or duplicate, veins that travel in parallel with the great and small saphenous veins), the deep system (popliteal and femoral veins), and perforator veins that cross through the fascia and connect the deep and superficial systems. One-way valves are present within all veins to direct the return of blood up the lower limb. Because the venous pressure in the deep system is generally greater than that of the superficial system, valve incompetence at any level may lead to backflow (venous reflux) with pooling of blood in superficial veins. Varicose veins with visible varicosities may be the only sign of venous reflux, although itching, heaviness, tension, and pain may also occur. Chronic venous insufficiency secondary to venous reflux can lead to thrombophlebitis, leg ulcerations, and hemorrhage. The CEAP classification of venous disease considers the clinical, etiologic, anatomic, and pathologic characteristics of venous insufficiency, ranging from class 0 (no visible sign of disease) to class 6 (active ulceration).

Treatment of Saphenous Veins and Tributaries

Saphenous veins include the great and small saphenous and accessory saphenous veins that travel in parallel with the great or small saphenous veins. Tributaries are veins that empty into a larger vein. Treatment of venous reflux has traditionally included the following:

- Identification by preoperative Doppler ultrasonography of the valvular incompetence.
- Control of the most proximal point of reflux, traditionally by suture ligation of the incompetent saphenofemoral or saphenopopliteal junction.
- Removal of the superficial vein from circulation, e.g., by stripping of the great and/or small saphenous veins.
- Removal of varicose tributaries (at the time of the initial treatment or subsequently) by stab avulsion (phlebectomy) or injection sclerotherapy.

Minimally invasive alternatives to ligation and stripping have been investigated. These include forms of sclerotherapy, and thermal ablation using cryotherapy, high-frequency radio waves (200 to 300 kHz), or laser energy.

Coil Embolization

Coil embolization involves catheter placement into a calf or leg vein, followed by insertion of a small coil into the catheter that is guided into the vein. An injection of alcohol or a foamed sclerosant drug is typically used during the procedure resulting in vein occlusion.

Cryoablation (Cryostripping)

Cryoablation (cryostripping) is a technique based on the insertion of a probe through a very small skin incision or is applied externally to vessel wall. Top of the probe decreases temperature to -80 ºC resulting in cryoapplication effect, i.e., sticking of the surrounding tissues to the probe.

Endovenous Mechanochemical Ablation

Endovenous mechanochemical ablation uses both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced to the saphenofemoral junction. As the catheter is pulled back, a wire rotates at 3500 rpm within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, and results in less pain and risk of nerve injury without the need for the tumescent anesthesia used with endovenous thermal ablation techniques (RFA, endovenous laser ablation).

The KAVS [catheter-assisted vein sclerotherapy] procedure involves an intravascular catheter that is introduced into the vein for short-term therapeutic use. The catheter has a balloon at the distal end that will temporarily block the blood flow to that segment of the vein being targeted for sclerotherapy. Evidence evaluating the safety and efficacy of endovenous catheter-directed chemical ablation in conjunction with balloon isolation as a treatment of varicose veins is not a widely accepted practice approach in the medical community.

Regulatory Status

In 2008, the ClariVein Infusion Catheter (Vascular Insights) was approved by the U.S. Food and Drug Administration (FDA) through the 510(k) process for mechanochemical ablation.

In 2005, a modified Erbe Erbokryo cryosurgical unit (Erbe USA) was approved by the U.S. Food and Drug Administration (FDA) through the 510(k) process. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs.

In 2005, the KAVS catheter was approved by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The KAVS Catheter is intended to temporarily inhibit blood flow in isolated sections of peripheral veins in order to inject physician prescribed medications.

RATIONALE

This evidence review was created in August 201 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through July 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Alternatives to Ligation and Stripping

Clinical Context and Therapy Purpose

The purpose of the following procedures below in individuals who have varicose veins/venous insufficiency is to provide treatment option that is an alternative to or an improvement on existing treatments:

- Coil embolization
- Cryoablation (cryostripping)
- Endomechanical ablative approaches using rotating catheter (e.g., ClariVein Catheter) (e.g., mechanical occlusion chemically assisted ablation [MOCA], mechanic-chemical endovenous ablation [MCEA], mechanically enhanced endovenous chemical ablation [MEECA)
- Endovenous catheter directed chemical ablation with balloon isolation (e.g., KAVS procedure)

The following PICO was used to select literature to inform this review.

Populations

The relevant populations of interest are those who have varicose veins/venous insufficiency and saphenous vein reflux.

Interventions

The therapies being considered are the following:

- Coil embolization
- Cryoablation (cryostripping)
- Endomechanical ablative approaches using rotating catheter (e.g., ClariVein Catheter) (e.g., mechanical occlusion chemically assisted ablation [MOCA], mechanic-chemical endovenous ablation [MCEA], mechanically enhanced endovenous chemical ablation [MEECA)

- Endovenous catheter directed chemical ablation with balloon isolation (e.g., KAVS procedure)

Comparators

Established treatments for varicose veins/venous insufficiency are conservative therapy with compression bandages and ligation and stripping, with which the endovenous thermal procedures are compared. The less invasive endovenous thermal ablation (radiofrequency or laser) have become the standard treatments by which the newer treatments are compared. Endovenous thermal ablation techniques require tumescent anesthesia, which involves multiple injections along the vein and is associated with moderate pain. Compression stockings and avoidance of strenuous activities are recommended. Procedures that have more recently been developed (MOCA, CAC, and cryotherapy) do not require tumescent anesthesia and are compared with thermal ablation procedures.

Outcomes

Outcomes of interest for venous interventions include healing and recurrence, recanalization of the vein, and neovascularization. Recanalization is the restoration of the lumen of a vein after it has been occluded; this occurs more frequently following treatment with endovenous techniques. Neovascularization is the proliferation of new blood vessels in tissue and occurs more frequently following vein stripping. Direct comparisons of the durability of endovenous and surgical procedures are complicated by these mechanisms of recurrence. Relevant safety outcomes include the incidence of paresthesia, thermal skin injury, thrombus formation, thrombophlebitis, wound infection, and transient neurologic effects.

Specific measures may include the visual analog score (VAS) for pain, the Venous Clinical Severity Score (VCSS), and the Aberdeen Varicose Veins Questionnaire (AVVQ). AVVQ scores range from 0 to 100 (worst possible quality of life). Follow-up at 1 and 2 years from RCTs is of interest to monitor treatment success (vein occlusion and recanalization), with follow-up to 5 years to assess the durability of treatment.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Coil Embolization

There is scant published literature addressing coil embolization for treatment of lower extremity veins. An early study by van Dijk and colleagues (1999) investigated percutaneous coil embolization of incompetent perforating veins to treat venous ulcers and recurrent varicosities in the lower leg. A total of 15 individuals with 18 incompetent perforating veins in the lower leg were treated by ultrasound-guided percutaneous

placement of embolization coils. Successful vein occlusion with one or more coils occurred in 12 of the 18 veins (technical success rate, 67%). Clinical symptoms improved in only 3 of the 15 individuals (clinical success rate, 20%). During follow-up at 2-12 months, recanalization of coil-embolized veins occurred in 9 of the 12 initially occluded veins. Another small study (Viani, 2014) consisted of 9 individuals and evaluated a “one-shot scleroembolization” technique designed to treat lower extremity varicose veins. The technique combined the use of a coil positioned in the terminal portion of the GSV and a foamed sclerosant drug. At 3 months’ follow-up, there were no complications reported and the GSV remained occluded in all cases. Currently, coil embolization is not an approach widely accepted by the practicing medical community for the treatment of varicose veins.

Section Summary: Coil Embolization

There is scant published literature addressing coil embolization for treatment of lower extremity veins.

Cryoablation

Randomized Controlled Trials

Klem et al (2009) reported on a randomized trial that found endovenous cryoablation (n=249) to be inferior to conventional stripping (n=245) for treating patients with symptomatic varicose veins. Forty-four percent of patients had residual great saphenous vein remaining with cryoablation while 15% had residual vein remaining with conventional stripping. AVVQ scores also showed better results for conventional stripping (score, 11.7) than cryoablation (score, 8.0). There were no differences between groups in 36-Item Short-Form Health Survey summary scores or neural damage (12% in both groups).

Disselhoff et al (2008, 2011) reported on 2- and 5-year outcomes from a randomized trial that compared cryoablation with endovenous laser ablation. Included were 120 patients with symptomatic uncomplicated varicose veins (CEAP class C2) with saphenofemoral incompetence and great saphenous vein reflux. At 10 days after treatment, endovenous laser ablation provided better results than cryoablation with respect to pain scores over the first 10 days (2.9 vs. 4.4), resumption of normal activity (75% vs. 45%), and induration (15% vs. 52%), all respectively. At a 2-year follow-up, freedom from recurrent incompetence was observed in 77% of patients after endovenous laser ablation and in 66% of patients after cryoablation (p= not significant). At 5 years, 36.7% of patients were lost to follow-up; freedom from incompetence and neovascularization were found in 62% of patients treated with endovenous laser ablation and in 51% of patients treated with cryoablation (p= not significant). Neovascularization was more common after cryoablation, but incompetent tributaries were more common after endovenous laser ablation. There were no significant differences between groups in the Venous Clinical Severity Score or AVVQ scores at either the 2 or 5-month follow-up for endovenous laser ablation.

Section Summary: Cryoablation

Two RCTs have suggested that cryotherapy is ineffective for treating varicose veins compared with available alternatives.

Mechanochemical Ablation

In a Hayes Inc. health technology assessment (February 2024) regarding mechanochemical endovenous ablation (MOCA) with the ClariVein infusion catheter non-thermal vein ablation system (Merit Medical Systems Inc.) for the treatment of varicose veins this assessment included 4 RCTs, 2 retrospective

comparative studies, 1 single-arm pretest and post-test study and systematic reviews published 2020 or later which was 2 studies. This assessment found that the quality of evidence was rated low due to limited evidence on long-term durability and reintervention and lack of comparative effectiveness and safety for MOCA compared to other nonthermal therapies. While these studies may show promise in the short term the current evidence does not allow conclusions as it relates to long-term efficacy. Comparative RCTs are needed with larger sample sizes, longer follow-up and comparing MOCA using ClariVein with other non-thermal clinical alternatives to determine safety and efficacy of this therapy in the treatment of varicose veins.

Randomized Controlled Trials

Four RCTs with over 100 patients each (range, 132 to 213) have been identified that compared MOCA to thermal ablation. Study characteristics and study results are presented in Tables 1 and 2. Study limitations are described in Tables 8 and 9.

Two publications (Bootun et al [2016], Lane et al [2017]) reported on early results from an RCT of 170 patients that compared ClariVein with RFA. Maximum VAS pain scores (out of 100) during the procedure were significantly lower in the MOCA group (median, 15 mm) than in the RFA group (median, 34 mm; p=.003). Average VAS pain scores during the procedure were also modestly lower in the MOCA group (median, 10 mm) than in the RFA group (median, 19.5 mm; p=.003). Occlusion rates, clinical severity scores, disease-specific quality of life, and generic quality of life scores were similar between the groups at 1 and 6 months. Limitations of this study are described in Tables 3 and 4. Only 71% of patients were available for follow-up at 6 months, limiting the evaluation of closure rates at this time point.

Vahaaho et al (2019) reported an RCT that compared MOCA with endovenous thermal ablation (endovenous laser ablation or RFA).[,] Liquid sclerosant at a concentration of 1.5% was used. Out of 132 patients enrolled, 7 patients were later excluded and 117 (88.6%) attended the 1-year follow-up evaluation. Occlusion of the great saphenous vein was observed in 45 of 55 (82%) of the MOCA group compared to 100% of the endovenous laser ablation and RFA groups (p=.002). Another randomized trial (Lam et al [2016]) reported interim results of a dose-finding study, finding greater closure with the use of polidocanol 2% or 3% (liquid) than with polidocanol 1%. Therefore, it is uncertain whether the concentration of sclerosant in the study by Vahaaho et al (2019) was optimal.

Three percent polidocanol was tested in the Mechanochemical endovenous Ablation to RADiOfrequeNcy Ablation (MARADONA) non-inferiority trial reported by Holewijn et al (2019). Although the study was powered for 400 participants, only 213 patients were randomized before reimbursement for the procedure was suspended. Pain scores in the 14 days after the procedure were slightly lower, but hyperpigmentation was higher. Anatomic failures were significantly greater in the MOCA group at 1 year and approached significance at 2 years; with the note that the study was underpowered for anatomic failures because of the early stoppage of the study. At 1 and 2 years, clinical and quality of life outcomes were similar in the 2 groups.

A fourth RCT reported by Mohamed et al (2020) is the ongoing Randomized Clinical Trial Comparing Endovenous Laser Ablation and Mechanochemical Ablation (ClariVein) in the Management of Superficial Venous Insufficiency (LAMA). Patients (n=150) were randomized to MOCA with 1.5% sodium tetradecyl sulfate or to endovenous laser ablation. Anatomic success (occlusion) rates were lower in the MOCA group (77%) compared to the endovenous laser ablation group (91%) with no significant difference between the 2 treatments in intraprocedural pain scores. In contrast to the difference in anatomical occlusion rates, clinical severity and quality of life scores were not significantly different between the groups at 1 year follow-up. Follow-up is continuing to evaluate the durability of the treatments.

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Booton et al (2016), Lane et al (2017)				170 patients with varicose veins	MOCA	RFA
Vahaaho et al (2019)				132 patients with varicose veins	MOCA with 1.5% polidocanol	Thermal ablation (endovenous laser ablation or RFA)
Holewijn et al (2019) (MARADONA)	EU	4	2012-2015	213 patients with great saphenous vein incompetence and CEAP C2 to C5	MOCA with 2 mL of 3% polidocanol for the first 10 to 15 cm and 1.5% polidocanol for the remainder	RFA
Mohamed et al (2020) (LAMA)	UK	1	2015-2018	150 patients with symptomatic superficial venous incompetence CEAP grades 2 to 6	MOCA (n=75) with 1.5% sodium tetradecyl sulfate	Endovenous laser ablation (n=75)

CEAP: clinical etiologic anatomic pathological; LAMA: A Randomised Clinical Trial Comparing Endovenous Laser Ablation and Mechanochemical Ablation (ClariVein) in the Management of Superficial Venous Insufficiency; MARADONA: Mechanochemical endovenous Ablation to RADiOfrequeNcy Ablation; MOCA: mechanochemical ablation; RCT: randomized controlled trial; RFA: radiofrequency ablation.

Table 2. Summary of Key RCT Results

Study	Pain	Post-procedure Occlusion Rate	Occlusion Rate at Follow-up	Clinical Severity	Clinical Severity at Follow-up		Quality of Life
Booton et al (2016), Lane et al (2017)	During Procedure - VAS		6 mo occlusion rates				
N			71%		71%		
MOCA	10 mm						
RFA	19.5 mm						
p-value	.003	NS	NS	NS	NS		NS
Vahaaho et al (2019)			1 yr		1 yr		
N			117 (88.6%)		117 (88.6%)		
MOCA			45 of 55 (82%)				
Endovascular laser ablation or RFA			100%				
p- value			.002				
Holewijn et al (2019) (MARADONA)	For 14 days after the procedure median (range)	30 day failure rate	1 yr recanalization rate	2 yr recanalization rate	1 yr VCSS	2 yr VCSS	AVVQ improved

Study	Pain	Post-procedure Occlusion Rate	Occlusion Rate at Follow-up	Clinical Severity	Clinical Severity at Follow-up		Quality of Life
N			153 (72%)	157 (73%)	153 (72%)	157 (73%)	
MOCA	0.2 (0.0 to 0.8)	5 (4.9%)	15 (16.5%)	21 (20%)	1.8	1.0	88%
RFA	0.5 (0.2 to 1.3)	1 (1%)	5 (5.8%)	12 (11.7%)	1.7	1.0	89%
p- value	.01	.10	.025	.066	.695	.882	.90
Mohamed et al (2020) (LAMA)	Median (IQR)		Occlusion at 1 yr		VCSS		AVVQ Median (IQR)
N			138 (92%)				
MOCA	15 (9 to 29)		53/69 (77%)				2.0 (0.0 to 5.3)
Endovascular laser ablation	22 (9 to 44)		63/69 (91%)				2.0 (0.0 to 4.8)
p- value	.21		.020		NS		NS

AVVQ: Aberdeen varicose vein questionnaire; IQR: intraquartile range; LAMA: A Randomized Clinical Trial Comparing Endovenous Laser Ablation and Mechanochemical Ablation (ClariVein) in the Management of Superficial Venous Insufficiency; MARADONA: Mechanochemical endovenous Ablation to RADiOfrequeNcy Ablation; MOCA: mechanochemical ablation; NS: not significant; RCT: randomized controlled trial; RFA: radiofrequency ablation; VAS: visual analog scale.; VCSS: venous clinical severity score.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Bootun et al (2016); Lane et al (2017)				1.Primary outcome was pain during the procedure	1. Outcomes only out to 6 mo, which is insufficient to assess durability
Vahaaho et al (2019)	4. Strict inclusion criteria that may not be representative of intended use.	3. The concentration of sclerosant (1.5% polidocanol) may not have been optimal.			1. Outcomes only out to 1 yr, which is insufficient to assess durability
Holewijn et al (2019), (MARADONA)	4. Patients with bilateral reflux were excluded due to dosing limits of polidocanol				
Mohamed et al (2020) (LAMA)					1. Outcomes out to 1 yr, follow-up is continuing

LAMA: A Randomized Clinical Trial Comparing Endovenous Laser Ablation and Mechanochemical Ablation (ClariVein) in the Management of Superficial Venous Insufficiency; MARADONA: Mechanochemical endovenous Ablation to RADiOfrequeNcy Ablation.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b]Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Bootun et al (2016), Lane et al (2017)		1. Patients not blinded to treatment (assessors of duplex ultrasound were blinded)		1. There was high loss to follow-up (76% follow-up at 1 mo and 71% follow-up at 6 mo)		
Vahaaho et al (2019)		1, 2, 3. Patients, surgeons, and assessors were not blinded to treatment				
Holewijn et al (2019) , (MARADONA)		1, 2, 3. Patients, surgeons, and assessors were not blinded to treatment			3. Underpowered for anatomic success due to early termination of recruitment	4. Results of noninferiority analysis were not reported
Mohamed et al (2020) (LAMA)		1, 2, 3. Patients, surgeons, and assessors were not blinded to treatment				2. 14-day pain scores were not analyzed by repeated measures ANOVA

ANOVA: analysis of variance; LAMA: A Randomised Clinical Trial Comparing Endovenous Laser Ablation and Mechanochemical Ablation (ClariVein) in the Management of Superficial Venous Insufficiency; MARADONA: Mechanochemical endovenous Ablation to RADiOfrequeNcy Ablation.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b]Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d]Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. s and/or p values not reported; 4.Comparative treatment effects not calculated.

Prospective Cohort Studies

Oud et al (2025) reported on a single-center, prospective cohort study evaluating the long-term effectiveness of MOCA using the ClariVein device for treating great saphenous vein incompetence. The study had a mean follow-up of 8.4 years and was conducted as a continuation of a previous multicenter RCT, including 109 patients (115 treated limbs) who underwent treatment between 2012 and 2018. The primary outcome was anatomical success, defined as complete closure of the treated vein or a partially reopened segment measuring <10 centimeters. A secondary measure, called reflux-free anatomical success, required that any reopened segment did not show backward blood flow. Results are reported in Table 8. Approximately 7% of patients required repeat interventions due to treatment failure.

A prospective cohort study that had a 5-year follow-up was reported by Thierens et al (2019). Anatomic and clinical follow-ups were performed at 4 weeks, 6 months, and 1, 3, and 5 years after the procedure (Table11). With slightly less than half of the participants remaining in the study through 5 years, 79% had freedom from anatomic failure and clinical measures had worsened. Nearly 15% of the recanalizations occurred in the first year, which the authors considered to be due to technical issues when the procedure was initially introduced. For example, there had been an increase in the concentration of sclerosant over time. It should be noted, however, that the more recent MARADONA trial from the same group of investigators using 3% polidocanol (described above) also saw a rate of recanalization of 16.5% in the first year and 20% in the second year. Without a control condition, it cannot be determined whether the loss of clinical improvement in this cohort study is due to recanalization or the usual progression of venous disease over time.

Study inclusion criteria are described in Table 5.

Table 5. Summary of Prospective Cohort Study Characteristics

Study	Country	Participants	Treatment Delivery	Follow-Up
Oud et al (2025)	Netherlands	Great saphenous vein insufficiency determined by duplex ultrasound examination	MOCA with 2% polidocanol or 3% polidocanol as sclerosant	Mean, 8 yr
Thierens et al (2019)	Netherlands	C2 to C5 varicose veins, great saphenous vein diameter of 3 to 12 mm and primary great saphenous vein insufficiency determined by duplex ultrasound examination	MOCA with 2% polidocanol as sclerosant	5 yr

MOCA: mechanochemical ablation.

Table 6. Summary of Prospective Cohort Study Results

Outcome Measure	Baseline	<6 months	1 yr	3 yr	5 yr	8 yr
Oud et al (2025)	n=109 patients (115 limbs)					
Anatomical success		88.5% (100/113 limbs)				60.5% (69/114 limbs)
Reflux-free anatomical success		NR				72.8% (83/114 limbs)
VCSS score	5.3					4.1
DVAAQ	13.5					10.5

Thierens et al (2019)	n=94		90	71	58	
Freedom from anatomic failure (SE)			85.6% (0.033)	80.1% (0.039)	78.7% (0.041)	
AVVQ score	8.9		2.3	5.6	6.3	
VCSS score	4.0		1.0	1.0	2.0	
Clinical improvement			80%	74%	65%	

AVVQ: Aberdeen varicose vein questionnaire; DVAAQ: Dutch version of the Aberdeen Varicose Vein Questionnaire; NR: not reported; SE: standard error; VCSS: venous clinical severity score.

Section Summary: Mechanochemical Ablation

MOCA is a combination of liquid sclerotherapy and mechanical abrasion of the lumen. The evidence on MOCA includes 4 RCTs that compared MOCA to thermal ablation with 6 months to 2-year results, and 2 prospective cohorts with follow-up out to 8 years. Results to date have been mixed regarding a reduction in intraprocedural pain, which is a proposed benefit of MOCA compared to thermal ablation procedures. Occlusion rates at 6 months to 2 years in the RCTs indicate lower anatomic success rates compared to thermal ablation, but a difference in clinical outcomes at these early time points has not been observed. Experience with other endoluminal ablation procedures suggests that lower anatomic success in the short term is associated with recanalization and clinical recurrence between 2 to 5 years. The possibility of later clinical recurrence is supported by prospective cohort study with up to 8-year follow-up following treatment with MOCA. However, there have been improvements in technique since the cohort studies began, and clinical progression is frequently observed with venous disease. Because of these limitations, longer follow-up of the more recently conducted RCTs is needed to establish the efficacy and durability of this procedure compared with the criterion standard of thermal ablation.

The KAVS [catheter-assisted vein sclerotherapy] procedure involves an intravascular catheter that is introduced into the vein for short-term therapeutic use. The catheter has a balloon at the distal end that will temporarily block the blood flow to that segment of the vein being targeted for sclerotherapy. Evidence evaluating the safety and efficacy of endovenous catheter-directed chemical ablation in conjunction with balloon isolation as a treatment of varicose veins is not a widely accepted practice approach in the medical community.

KAVS (Catheter-assisted Vein Sclerotherapy) Procedure

No studies were identified that evaluated the comparative efficacy and safety of the KAVS (catheter-assisted vein sclerotherapy) procedure in comparison to conservative care. Although a single case series published by Brodersen et al (2007) reported successful greater saphenous vein closure in 90% of 30 patients treated with KAVS at 6 weeks, 3-months, and 6 months follow-up periods and no serious adverse effects, further comparative evidence is needed to better clarify the net health benefit of this procedure.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Vein and Lymphatic Society

In 2015, the American Vein and Lymphatic Society (AVLS) (previously named the American College of Phlebology) published guidelines on the treatment of superficial vein disease.

In 2025, AVLS published a position statement on mechanochemical chemically assisted ablation of varicose veins for venous insufficiency. The following conclusion and recommendations were made: "Mechanical occlusion chemically assisted venous ablation is effective in alleviating symptoms and a safe treatment option for venous insufficiency. As a non-thermal ablation method, MOCA [mechanical occlusion chemically assisted ablation] obviates the need for tumescent anesthesia and thus results in less procedural discomfort and risk of thermal nerve or skin injury. It may be used in both the below knee distal GSV [great saphenous veins] as well as the SSV [small saphenous veins] with no risk of thermal injury to the adjacent nerves. However, it is associated with significantly lower rates of vessel closure and higher recanalization rates when followed for more than 1 year compared to both radiofrequency ablation and endovenous laser ablation." "It is an available option for those in whom thermal ablation is not suitable."

Society for Vascular Surgery, American Vein and Lymphatic Society, and American Venous Forum

The Society for Vascular Surgery and the American Venous Forum (2011) published joint clinical practice guidelines. Table 11 provides the recommendations.

Table 11. Guidelines on the Management of Varicose Veins and Associated Chronic Venous Diseases

Recommendation	Grade[a]	SOR	QOE
Compression therapy for venous ulcerations and varicose veins			
Compression therapy is recommended as the primary treatment to aid healing of venous ulceration	1B	Strong	Moderate
To decrease the recurrence of venous ulcers, ablation of the incompetent superficial veins in addition to compression therapy is recommended	1A	Strong	High
Use of compression therapy for patients with symptomatic varicose veins is recommended	2C	Weak	Low
Compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation is not recommended	1B	Strong	Moderate
Treatment of the incompetent great saphenous vein			
Endovenous thermal ablation (radiofrequency or laser) is recommended over chemical ablation with foam or high ligation and stripping due to reduced convalescence and less pain and morbidity. Cryostripping is a technique that is new in the United States, and it has not been fully evaluated.	1B	Strong	Moderate

Recommendation	Grade[a]	SOR	QOE
Varicose tributaries			
Phlebectomy or sclerotherapy are recommended to treat varicose tributaries	1B	Strong	Moderate
Transilluminated powered phlebectomy using lower oscillation speeds and extended tumescence is an alternative to traditional phlebectomy	2C	Weak	Low
Perforating vein incompetence			
Selective treatment of perforating vein incompetence in patients with simple varicose veins is not recommended	1B	Strong	Moderate
Treatment of pathologic perforating veins (outward flow of ≥500 ms duration, with a diameter of ≥3.5 mm) located underneath healed or active ulcers (CEAP class C5-C6) is recommended	2B	Weak	Moderate

CEAP: Clinical Etiology Anatomy Pathophysiology; QOE: quality of evidence; SOR: strength of recommendation.
[a] Grading: strong = 1 or weak = 2, based on a level of evidence that is either high quality = A, moderate quality = B, or low quality = C.

The Society for Vascular Surgery, the American Vein and Lymphatic Society (AVLS), and the American Venous Forum published a joint clinical practice guideline in 2022 on management of lower extremity varicose veins. The guideline will be published in sections; the first part (published in 2022) focuses on duplex scanning and treatment of superficial truncal reflex. The second part of the guideline has not yet been published. Superficial truncal veins are defined as the great saphenous vein, small saphenous vein, anterior accessory great saphenous vein, and posterior accessory great saphenous vein. A summary of the guideline recommendations is provided in Table 12.

Table 12. Summary of Recommended Treatment of Superficial Truncal Reflex

Recommendation	Grade[a]	SOR	QOE
Symptomatic varicose veins and axial reflux			
Reflux in the great or small saphenous vein - superficial venous intervention preferred over long-term compression stockings	1B	Strong	Moderate
Reflux in the anterior accessory or posterior accessory great saphenous vein - superficial venous intervention preferred over long-term compression stockings	2C	Weak	Low
Reflux in the superficial truncal vein - compression therapy suggested for primary treatment	2C	Weak	Low
Reflux in the great saphenous vein - endovenous ablation preferred over high ligation and stripping[b]	1B	Strong	Moderate
Reflux in the small saphenous vein - endovenous ablation preferred over high ligation and stripping[b]	1C	Strong	Low
Reflux in the anterior accessory or posterior accessory great saphenous vein - endovenous ablation (with phlebectomy if needed) over ligation and stripping[b]	2C	Weak	Low
Patients who place a high priority on long-term outcomes (quality of life and recurrence) - laser ablation, radiofrequency ablation, or ligation and stripping over ultrasound-guided foam sclerotherapy	2C or 2B	Weak	Moderate or Low
Symptomatic axial reflux			
Reflux in the great saphenous vein - thermal and nonthermal ablation recommended	1B	Strong	Moderate
Reflux in the small saphenous vein - thermal and nonthermal ablation recommended	1C	Strong	Low

Recommendation	Grade[a]	SOR	QOE
Reflux in the anterior accessory or posterior accessory great saphenous vein - either thermal or nonthermal ablation suggested	2C	Weak	Low
Varicose veins (CEAP class C2)			
Reflux in the great or small saphenous vein - recommend against concomitant initial ablation and treatment of incompetent perforating veins	1C	Strong	Low
Reflux in the anterior accessory or posterior accessory great saphenous vein - recommend against concomitant initial ablation and treatment of incompetent perforating veins	2C	Weak	Low
Persistent or recurrent symptoms after previous complete ablation - treatment of perforating vein incompetence suggested	2C	Weak	Low
Symptomatic reflux and associated varicosities			
Reflux in the great or small saphenous vein - ablation and concomitant phlebectomy or ultrasound-guided foam sclerotherapy recommended	1C	Strong	Low
Reflux in the anterior accessory or posterior accessory great saphenous vein - ablation and concomitant phlebectomy or ultrasound-guided foam sclerotherapy suggested	2C	Weak	Low

CEAP: Clinical Etiology Anatomy Pathophysiology; QOE: quality of evidence; SOR: strength of recommendation. [a] Grading: strong = 1 or weak = 2, based on a level of evidence that is either high quality = A, moderate quality = B, or low quality = C. b Ligation and stripping can be performed if endovenous ablation is not feasible.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring percutaneous, mechanochemical; first vein treated (Mechanochemical Ablation [MCA; MOCA] (ClariVein System)
	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) (Mechanochemical Ablation [MCA; MOCA] (ClariVein System)
	37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g., congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles) (may be utilized for coil embolization)

	37799	Unlisted procedure, vascular surgery (may be utilized for Trannsilluminated Powered Phlebectomy ([TIPP, TriVex]; or cryostripping [cryoablation, cryofreezing and transilluminated cryosurgery])
	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 (KAVS Procedure)
	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
	76942	Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation
	77002	Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device) (List separately in addition to code for primary procedure)
HCPCS		
	None	
Type of Service	Surgery	
Place of Service	Outpatient/Inpatient	

POLICY HISTORY

Date	Action	Action
January 2026	Interim Review	Policy Revised
July 2025	Annual Review	Policy Revised
July 2024	Annual Review	Policy Renewed
July 2023	Annual Review	Policy Revised
May 2022	Annual Review	Policy Revised
May 2021	Annual Review	Policy Revised
May 2020	Annual Review	Policy Revised

Date	Action	Action
May 2019	Annual Review	Policy Revised
May 2018	Annual Review	Policy Revised
February 2018	Interim Review	Policy Revised
May 2017	Annual Review	Policy Revised
June 2016	Annual Review	Policy Revised
July 2015	Annual Review	Policy Revised
September 2014	Interim Review	Policy Revised
August 2014		New Medical Policy Created

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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