Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 7/1/23**
(See policy history boxes for previous effective dates)

Title: Endovenous Ablation for the Treatment of Varicose Veins (e.g., ClariVein®, VenaSeal™ Closure System)

Description/Background

Varicose veins are enlarged and twisted vessels that develop when the thin flaps of the venous valves no longer meet in the midline, allowing blood to reflux, or flow in a retrograde direction. Varicose veins may be associated with pain, itching, muscle cramps, edema, pigmentation, eczema, superficial or deep venous thrombosis, induration and/or ulceration. Great saphenous vein (GSV) reflux is most commonly responsible for the development of varicose veins. Treatments for symptomatic varicose veins of the legs include conservative measures such as using compression hosiery elevating the legs, walking, and management weight. In cases where there is severe discomfort, ulceration, or thrombosis, excision or ablation of the affected veins may be required.

Endovenous Mechanochemical Ablation (MOCA)
The ClariVein® Occulsion Catheter is used to perform endovenous mechanochemical ablation (MOCA) of varicose veins. MOCA, a nonthermal technique, combines endomechanical abrasion produced by the tip of a catheter's rotating wire (mechanical component) with endovenous chemical ablation delivered simultaneously via injection of sclerosant over the rotating wire (chemical component). MOCA induces sclerosis of the endothelium, which activates the clotting system, resulting in formation of a thrombus and consequent occlusion of the diseased vein.

The ClariVein system comprises two devices, both of which are single-use and disposable. One component is a small profile infusion catheter (< 3Fr) with a rotating wire, and a cartridge. The second component is a motor-drive unit powered by an internal 9-volt battery contained in a plastic handpiece. With local anesthetic delivered only to the access site, the infusion catheter is introduced into the vein percutaneously through a microintroducer under ultrasonographic guidance. After the catheter is steered to the treatment site, the rotating tip abrades the endothelium and the area is infused with sclerosant. The catheter is slowly withdrawn, and ultrasonography (US) confirms sealing of the vein. The ClariVein is used by a vascular surgeon or other qualified physician in an office or

other outpatient setting. After the procedure, patients may return to their usual activities immediately but are instructed to wear compression stockings for the first 24 hours and during the day for 2 weeks.

Endovenous Ablation by Chemical Adhesive (e.g., cyanoacrylate, VenaSeal™)
The VenaSeal™ closure system is indicated for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with coaptation. The VenaSeal system is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound (DUS).

The VenaSeal closure system is a medical device provided as a sterile, single patient kit comprised of the VenaSeal adhesive and VenaSeal delivery system components. The kit is designed to be used as a system, and its contents are not intended for use as individual components. The VenaSeal system is intended to be used by a licensed physician while using high resolution ultrasound imaging. The VenaSeal system is indicated for the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with coaptation. The VenaSeal system is intended for use in adults with clinically symptomatic venous reflux.

Regulatory Status

The ClariVein® Infusion Catheter (Vascular Insights LLC) (K071468) was cleared by the FDA on March 20, 2008. The ClariVein Infusion Catheter is often called the ClariVein Occlusion Catheter. This technique goes by many names, e.g., endovenous mechanochemical ablation (MOCA, as used in this report), mechanico-chemical endovenous ablation (MCEA), and mechanically enhanced endovenous chemical ablation (MEECA).

The VenaSeal™ Closure System was cleared by the FDA on February 20, 2015. The VenaSeal System is intended to permanently treat varicose veins of the legs that cause symptoms by sealing the affected veins that are closest to the skin (superficial varicose veins) with a cyanoacrylate-based adhesive. The VenaSeal System also consists of a catheter, guidewire, dispenser gun, dispenser tips, and syringes.

Medical Policy Statement

Endovenous ablation of varicose veins by mechanochemical (ClariVein®) is experimental/investigational. This procedure has not been scientifically demonstrated to be as safe and effective as conventional treatment.

Endovenous ablation of varicose veins by chemical adhesive (Cyanoacrylate, VenaSeal™) is established in patients with symptomatic varicose veins/venous insufficiency when the below criteria is met.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Great or Small Saphenous Veins

cyanoacrylate adhesive may be considered established for symptomatic varicose veins/venous insufficiency when the following criteria have been met:

- There is demonstrated saphenous reflux and CEAP [Clinical, Etiology, Anatomy, Pathophysiology] class C2 or greater; AND
- There is documentation of 1 or more of the following indications:
    - Ulceration secondary to venous stasis; OR
    - Recurrent superficial thrombophlebitis; OR
    - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; OR
    - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, AND
    - Conservative management therapy including compression therapy for at least 3 consecutive months, prior to surgical intervention, and has not improved the symptoms.
        - Conservative management must include a trial of compression therapy garments, or
        - Medical reason for compression therapy exemption is documented (e.g., existing chronic limb ischemia, severe musculoskeletal disability, morbid obesity, unusual leg anatomy)

Accessory Saphenous Veins

- Incompetence of the accessory saphenous vein is isolated, OR the great or small saphenous veins had been previously eliminated (at least 3 months); AND
- there is demonstrated accessory saphenous reflux; AND
- there is documentation of 1 or more of the following indications:
    - Ulceration secondary to venous stasis; OR
    - Recurrent superficial thrombophlebitis; OR
    - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; OR
    - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, AND
    - Conservative management therapy including compression therapy for at least 3 consecutive months, prior to surgical intervention, and has not improved the symptoms.
        - Conservative management must include a trial of compression therapy garments, or
        - Medical reason for compression therapy exemption is documented (e.g., existing chronic limb ischemia, severe musculoskeletal disability, morbid obesity, unusual leg anatomy)

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

36482 36483

Other codes (investigational, not medically necessary, etc.):

36473 36474

Rationale

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 (QOL), 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.

Clinical Context and Therapy Purpose
The purpose of mechanochemical ablation and cyanoacrylate adhesive in patients who have varicose veins/venous insufficiency and saphenous vein reflux is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICOs** were used to select literature to inform this review.

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

Interventions
The therapies being considered are mechanochemical ablation and cyanoacrylate adhesive.

Comparators
Established treatments for varicose veins/venous insufficiency and saphenofemoral junction reflux are conservative therapy with compression bandages and ligation and stripping, with which the endovenous procedures are compared. The less invasive endovenous thermal ablation (radiofrequency or laser) have become the standard treatments by which the newer treatments are compared. Compression stockings and avoidance of strenuous activities are recommended. Procedures that have more recently been developed (mechanochemical ablation (MOCA) and cyanoacrylate adhesive (CAC).

Outcomes
The general outcomes of interest for all interventions are reductions in symptoms and morbid events, change in disease status, and improvements in QOL. Specific measures may include the visual analog score (VAS) for pain, the Varicose Vein 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 one and two years from RCTs is of interest to monitor treatment success (vein occlusion and recanalization), with follow-up to 5 years to assess durability of the treatment.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with 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.

Endovenous Mechanochemical Ablation (MOCA) (CPT codes 36473 and 36474)
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 3 and 4.

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.[1,2] Maximum visual analog scale pain scores (out of 100) during the procedure were significantly lower in the mechanochemical ablation group (median, 15 mm) than in the RFA group (median, 34 mm; p=0.003). Average visual analog scale pain scores during the procedure were also modestly lower in the mechanochemical ablation group (median, 10 mm) than in the RFA group (median, 19.5 mm; p=0.003). Occlusion rates, clinical severity scores, disease-specific QOL, and generic QOL scores were similar between groups at one and six months. Limitations of this study are described in Tables 1 and 2. Only 71% of patients were available for follow-up at 6 months, limiting the evaluation of closure rates at this time point (see Table 2).

Vahaaho et al (2019) reported an RCT that compared mechanochemical ablation (MOCA) with endovenous thermal ablation (EVLA or RFA).[3] Liquid sclerosant at a concentration of 1.5% was used. Out of 132 patients enrolled, seven patients were later excluded and 117 (88.6%) attended the one-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 EVLA and RFA groups (p=0.002). Another randomized trial (Lam et al [2016]) reported interim results of a dose-finding study, finding greater closure with use of polidocanol 2% or 3% (liquid) than with polidocanol 1% (microfoam).[4] Therefore, it is uncertain whether the concentration of sclerosant in the study by Vahaaho et al (2019) was optimal (see Table 1).

Three percent policocanol was tested in the Mechanochemical endovenous Ablation to RADiOfrequeNcy Ablation (MARADONA) non-inferiority trial reported by Holewijn et al (2019).[28] Athough 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 two groups.
A fourth RCT reported by Mohamed et al (2020) is the ongoing Randomised Clinical Trial Comparing Endovenous Laser Ablation and Mechanochemical Ablation (ClariVein) in the Management of Superficial Venous Insufficiency (LAMA).[29] Patients (n=150) were randomized to MOCA with 1.5% sodium tetradecyl sulfate or to EVLA. Anatomic success (occlusion) rates were lower in the MOCA group 77% compared to the EVLA 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 durability of the treatments.

Table 3. 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 (EVLA or RFA)
Holewijn et al (2019) (MARADONA)	E.U.	4	2012-2015	213 patients with GSV incompetence and CEAP C2 - C5	MOCA wit 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	U.K.	1	2015-2018	150 patients with symptomatic superficial venous incompetence CEAP grades 2 to 6	MOCA (n=75) with 1.5% sodium tetradecyl sulfate	EVLA (n=75)

EVLA: endovenous laser ablation; CEAP: clinical etiologic anatomic pathological; GSV: Great saphenous vein; LAMA: A Randomised Clinical Trial Comparing Endovenous Laser Ablation and Mechanochemical Ablation (ClariVein) in the Management of Superficial Venous Insufficiency; 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 (2016) Lane (2017)	During Procedure - VAS		6 mo occlusion rates			
N			71%		71%	
MOCA	10 mm					

RFA	19.5 mm						
p-value	0.003	NS	NS	NS	NS		NS
Vahaaho (2019)							
N			117 (88.6%)		117 (88.6%)	N	
MOCA			45 of 55 (82%)				
EVLA or RFA			100%				
p-Value			0.002				
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
N			153 (72%)	157 (73%)	153 (72%)	157 (73%)	
MOCA	0.2 (0.0-0.8)	5 (4.9%)	15 (16.5%)	21 (20%)	1.8	1.0	88%
RFA	0.5 (0.2-1.3)	1 (1%)	5 (5.8%)	12 (11.7%)	1.7	1.0	89%
p-Value	0.01	0.10	0.025	0.066	0.695	0.882	0.90
Mohamed et al (2020) LAMA	Median (IQR)		Occlusion at 1 yr		VCSS		AWQ Median (IQR)
N			138 (92%)				
MOCA	15 (9-29)		53/69 (77%)				2.0 (0.0–5.3)
EVLA	22 (9–44)		63/69 (91%)				2.0 (0.0–4.8)
p-Value	0.21		0.020		NS		NS

AVVQ: Aberdeen varicose vein questionnaire; EVLA: endovenous laser ablation; IQR: intraquartile range; 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; NS: not significant; RCT: randomized controlled trial; RFA: radiofrequency ablation; VAS: visual analog scale.; VCSS: venous clinical severity score

Table 3 . 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.
Vahaaho et al (2019)	4.Strict inclusion criteria that may not be representative of intended use.	3.The concentration of sclerosant (1.5%) may not have been optimal.			
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

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive limitation 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]	Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Bootun et al (2016)[24]; Lane et al (2017)[25]		1.Patients not blinded to treatment (assessors of duplex ultrasound were blinded)		1.76% follow-up at 1 mo and 71% follow-up at 6 mo.		
Vahaaho et al (2019)[60]		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 non-inferiority 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

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive limitation 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] Follow-Up 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. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Prospective Cohort Studies

A prospective cohort study that had 5 year follow-up was reported by Thierens et al (2019).[30] Study inclusion criteria are described in Table 5. Anatomic and clinical follow-ups were performed at 4 weeks, 6 months, and 1, 3, and 5 years after the procedure. 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 has 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.[28] 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.

Table 5. Summary of Prospective Cohort Study Characteristics

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

GSV: Great saphenous vein; MOCA: mechanochemical ablation

Table 6. Summary of Prospective Cohort Study Results

Outcome Measure	Baseline	1 yr	3 yr	5 yr
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; MOCA: mechanochemical ablation; VAS: visual analog scale.; VCSS: venous clinical severity score; SE: standard error

Section Summary: Endovenous Mechanochemical Ablation (MOCA)

Mechanochemical ablation is a combination of liquid sclerotherapy and MOCA. The evidence on MOCA includes 4 RCTs that compared MOCA to thermal ablation with 6 months to 2 year results, a prospective cohort with follow-up out to 5 years, and retrospective case series. 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 mo 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 a prospective cohort study with 5-year follow-up following treatment with MOCA. However, there have been improvements in technique since the cohort study was begun, and clinical progression is frequently observed with venous disease. Because of these limitations of the single arm studies, longer follow-up in the more recently conducted RCTs is needed to establish the

efficacy and durability of this procedure compared with the criterion standard of thermal ablation.

Endovenous Ablation by Chemical Adhesive (e.g., cyanoacrylate, CAC) (CPT codes 36482, 36483)

The VenaSeal pivotal study (VeClose), a multicenter noninferiority trial with 222 patients, compared VenaSeal with RFA for the treatment of venous reflux.[8,9] The pivotal registration study for the VeClose study and follow-up through 24 months have been published.[8-11] These reports are summarized in Tables 3 and 4. The primary end point (the proportion of patients with complete closure of the target GSV at 3 months measured by ultrasound) was noninferior to RFA, with a 99% closure rate for VenaSeal compared with 96% for RFA. The secondary end point (intraoperative pain) was similar for both groups (2.2 on a 10-point scale for VenaSeal vs. 2.4 for RFA, p=0.11). Ecchymosis at day 3 was significantly lower in the cyanoacrylate group; 67.6% of patients treated with cyanoacrylate had no ecchymosis compared with 48.2% of patients following RFA (p<0.01). Scores on the AVVQ and Venous Clinical Severity Score improved to a similar extent in both groups. The mean time to return to work in a prospective cohort of 50 patients reported by Gibson and Ferris (2017) was 0.2 days.[12]

For the CAC and RFA groups, the complete occlusion rates were 97.2% and 97.0%. Freedom from recanalization was also similar between the two groups (p=0.08).[8] Twenty-four month results were reported by Gibson et al (2018), which included 171 patients (87 from CAC and 84 from RFA).[9] Thirty-six month results were reported by Morrison et al (2019), with follow-up on 146 (66%) patients (72 from CAC and 74 from RFA).[11] Loss to follow-up was similar in the two groups. The complete closure rates for CAC and RFA were 94.4% and 91.9% (p=0.005 for non-inferiority), respectively. Recanalization-free survival through 36 months was not statistically different for the two groups. No significant device- or procedure-related adverse events were reported for either group.

VariClose CAC was compared with RFA and EVLA by Eroglu and Yasim (2018) in an RCT with 525 patients (see Table 5).[13] Periprocedural outcomes showed a shorter intervention time, less pain, and shorter return to work with CAC compared to endovenous thermal ablation . There was no significant difference in occlusion rates between the three treatments at 6, 12, and 24 month follow-up.

Table 7 . Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
FDA SSED (2015), Morrison et al (2015, 2017, 2018); Gibson et al (2018)	US	10	2013-2014	Age ≥21 and ≤ 70 years with symptomatic1 GSV reflux and CEAP C2- C4b	108 VenaSeal CAC	114 RFA
Eroglu and Yasim (2018)	Asia	1	NR	525 patients ≥ 18 years with incompetence of the GSV (>5.5 mm in diameter) or SSV (>4 mm in diameter) and reflux >0.5 sec.	175 VariClose CAC	125 RFA and 125 EVLA

CAC: cyanoacrylate ; CEAP: Clinical Etiology Anatomy Pathophysiology; EVLA: endovenous laser ablation; GSV: great saphenous vein; NR: not reported; RCT: randomized controlled trial; RFA: radiofrequency ablation; SSV: small saphenous vein; SSED; Summary of Safety and Effectiveness Data;

[1]One or more of the following symptoms related to the target vein: aching, throbbing, heaviness, fatigue, pruritus, night cramps, restlessness, generalized pain or discomfort, swelling.
[2]Protocol mandated use of compression stockings for 7 days post-procedure

Table 8 . Periprocedural Outcomes

Eroglu and Yasim (2018)	Duration of Procedure min (sd)	Average Periprocedural Pain[1]	2 or More Analgesics Used Daily n (%)	1 Day to Return to Work n (%)	2 Days to Return to Work n (%)	3 or More Days to Return to Work n (%)
N	503	503	456	456	456	456
VariClose	15.3 (2.6)	1 (mild)	105 (62.5)	161 (95.8)	7 (4.2)	0 (0)
RFA	27.3 (7.7)	2 (moderate)	98 (65.8)	75 (50.3)	53 (35.6)	21 (14.1)
EVLA	35.0 (5.2)	2 (moderate)	105 (75.5)	105 (75.5)	24 (17.3)	10 (7.2)
p-Value	<0.001		0.1472	<0.0012		

[1]Scale of 1 to 4; [2]overall p-Value

Table 9 . Summary of Key RCT Results

Study	Vein Closure[1] n (%)	Vein Closure 12 months n (%)	Vein Closure 24 months n (%)	Vein Closure 36 months n (%) or VCSS	Device Related Event n (%)
FDA SSED (2015), Morrison et al (2015,2017; 2018); Gibson et al (2018)	**3 months**				
N	222	189	171	146	222
VenaSeal	107 (99.1%)[2]	92 (96.7%)	82/86 (95.3%)	68/72 (94.4%)	31 (27%)
RFA	109 (95.6%)[2]	91 (96.8%)	79/84 (94.0%)	68/74 (91.9%)	7 (6%)
Eroglu and Yasim (2018)	**6 months**			**VCSS at 24 months**	
N		503	456	456	
VariClose	98.1%	94.1%	95.1%	2.7	
RFA	94.7%	92.5%	94.2%	3.7	
EVLA	92.6%	90.9%	91.5%	3.5	
p-Value	NS	NS	NS	<0.001	

EVLA: endovenous laser ablation; NS: not significant; RCT: randomized controlled trial; RFA: radiofrequency ablation; VCSS: venous clinical severity score.
[1]Complete closure defined as Doppler ultrasound showing vein closure along entire treated vein segment with no discrete segments of patency exceeding 5 cm. Central laboratory confirmation.
[2] Used prespecified data imputation method (Last Observation Carried Forward)

Notable limitations of the studies are shown in Tables 6 and 7. The primary limitation of the pivotal study of VenaSeal is the loss to follow-up at 2 and 3 years, with equal loss to follow-up was similar in the two groups. The study by Eroglu and Yasim had unequal loss to follow-up after patients were informed of the treatment allocation. Different expectations in the CAC group compared to the control groups may have influenced subjective outcomes. In addition VariClose is not currently approved for marketing in the US; both CAC products use N-butyl cyanoacrylate.

Table 10. Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]

Morrison (2015), Morrison (2017), Gibson (2018), VeClose		1.Follow-up scheduled to continue to 3 years
Morrison (2018)		1.Follow-up continue to 60 months
Eroglu and Yasim (2018)	2.This specific cyanoacrylate product is not currently available in the US	

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive limitation 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 11. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Follow-Up[e]	Power[d]	Statistical[f]
Morrison (2015), Morrison (2017), Gibson (2018), VeClose		1,2,3.The outcome was assessed by the treating physician and patients were not blinded		1.>20% loss to follow-up		3.Variable reporting of CI and p values
Eroglu and Yasim (2018)		1,2,3.Patients were notified of the group assignment a day before the procedure		6.Not intent-to-treat analysis and unequal loss to follow-up. 21 patients did not receive the allocated intervention, 19 of whom were in the control groups		

The evidence gaps 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] Follow-Up 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. Interventions not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Interventions not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Eroglu et al (2017) reported closure rates of 94.1% at 30 months in a prospective cohort of 159 patients.[9] Thirty-three-month follow-up was reported by Zierau (2015) for 467 (58.7%) of 795

veins treated at 1 institution in Germany. [12] An inflammatory reddening of the skin was observed at 1 week posttreatment in 11.7% of cases. No permanent skin responses were observed. Of the 467 veins reexamined, the sealing rate was 97.7%. This series had a high loss to follow-up.

Section Summary: Endovenous Ablation by Chemical Adhesive

Evidence assessing CAC for the treatment of varicose veins and venous insufficiency includes a multicenter noninferiority trial with follow-up through 36 months, an RCT with follow-up through 24 months, and a prospective cohort with 30 month follow-up. The short-term efficacy of VenaSeal CAC has been shown to be noninferior to RFA at up to 36 month follow-up. At 24 and 36 months the study had greater than 20% loss to follow-up, but loss to follow-up was similar in the two groups at the long-term follow-up and is not expected to influence the comparative results. A second RCT (n=525) with the same active CAC ingredient (N-butyl cyanoacrylate) that is currently available outside of the US found no significant differences in vein closure between CAC and thermal ablation controls at 24 month follow-up. The CAC procedure and return to work were shorter and pain scores were lower compared to thermal ablation; the subjective pain scores may have been influenced by differing expectations in this study. A prospective cohort reported high closure rates at 30 months. Overall, results indicate that outcomes from CAC are at least as good as thermal ablation techniques, the current standard of care.

Summary of Evidence

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive MOCA, the evidence includes 4 RCTs with 6 mo to 2 yr results that compared MOCA to thermal ablation, a prospective cohort with follow-up out to 5 years, and retrospective case series. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and TRM. 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 mo to 2 year 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 a prospective cohort study with 5-year follow-up following treatment with MOCA. However, there have been improvements in technique since the cohort study was begun, and clinical progression is frequently observed with venous disease. Because of these limitations of the single arm studies, longer follow-up in 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 the effects of the technology on health outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive CAC, the evidence includes two RCTs and a prospective cohort. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. Evidence includes a multicenter noninferiority trial with follow-up through 36 months, an RCT with follow-up through 24 months, and a prospective cohort with 30 month follow-up. The short-term efficacy of VenaSeal CAC has been shown to be noninferior to RFA at up to 36 months. At 24 and 36 months the study had greater than 20% loss to follow-up, but loss to follow-up was similar in the two groups at the long-term follow-up and is not expected to influence the comparative results. A second RCT (n=525) with the same active CAC ingredient (N-butyl

cyanoacrylate) that is currently available outside of the US found no significant differences in vein closure between CAC and thermal ablation controls at 24 month follow-up. The CAC procedure and return to work were shorter and pain scores were lower compared to thermal ablation, although the subjective pain scores may have been influenced by differing expectations in this study. A prospective cohort reported high closure rates at 30 months. Overall, results indicate that outcomes from CAC are at least as good as thermal ablation techniques, the current standard of care. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 12.

Table 12. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03392753	RCT of MOCA versus Cyanoacrylate adhesive for the treatment of varicose veins	180	Dec 2020
NCT03835559	RCT comparing the clinical outcomes after cyanoacrylate closure and surgical stripping for incompetent saphenous veins	146	Feb 2021
NCT02345018	Primary insufficiency of the GSV with a diameter >/= 12mm, antero-lateral branches, or below the knee (MOCA-XL)	90	Dec 2020
NCT02627846	Laser ablation versus mechanochemical ablation trial (LAMA)	150	Sept 2030
NCT03820947[a]	Global, Post-Market, Prospective, Multi-Center, Randomized Controlled Trial of the VenaSeal™ Closure System vs. Surgical Stripping or Endothermal Ablation (ETA) for the Treatment of Early & Advanced Stage Superficial Venous Disease	806	Oct 2027
Unpublished			
NCT01459263	Early outcome of mechanochemical endovenous ablation (ClariVein-2)	100	Feb 2018 (completed)
NCT03722134	MOCA versus thermal ablation in patients with great saphenous vein insufficiency	132	Dec 2020
NCT01936168	MOCA versus radiofrequency ablation in the treatment of primary great saphenous vein incompetence (MARADONA)	213	Dec 2020

NCT: national clinical trial

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

Society for Vascular Surgery/American Venous Forum (SVS/AVF)[14]

In clinical guidelines on treatment of varicose veins and other venous diseases, the SVS/AVF state that compression therapy may be used for patients with symptomatic varicose veins, but is not recommended as primary treatment if the patient is a candidate for saphenous vein ablation. Endovenous thermal ablation (radiofrequency or laser) is recommended over

chemical ablation with foam or high ligation and inversion 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. The guidelines do not discuss MOCA.

National Institute for Health and Care Excellence (NICE)[15-17]
NICE clinical guidelines on endovenous mechanochemical ablation (MOCA) for varicose veins (May 2016) states that current evidence on the safety and efficacy appears to be adequate to support the use of this procedure provided that the standard arrangements are in place for consent, audit and clinical governance.

NICE clinical guidelines on cyanoacrylate glue occlusion for varicose veins (March 2020) states:
1.1 Evidence on the safety and efficacy of cyanoacrylate glue occlusion for varicose veins is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
1.2 The procedure should only be done by clinicians with appropriate training in this procedure and experience in the use of venous ultrasound.

Government Regulations
National:
No NCD on this topic.

Local:
WPS Local Coverage Determination (LCD) for Treatment of Varicose Veins of the Lower Extremities (L34536). For services on or after 09/30/21:

Historically, varicose veins have been treated by conservative measures such as exercise, periodic leg elevation, weight loss, compressive therapy and avoidance of prolonged immobility. When conservative measures are unsuccessful, and symptoms persist, the next step has been sclerotherapy or surgical ligation with or without stripping. Sclerotherapy involves the injection of a sclerosing solution into the varicose vein(s).

More recently, endoluminal radiofrequency ablation (ERFA) and endoluminal laser ablation have been developed as alternatives to sclerotherapy and surgical intervention. These procedures are designed to damage the intimal wall of the vein resulting in fibrosis and subsequent ablation of the lumen of a segment of the vessel. Both procedures utilize specially designed catheters inserted through a small incision in the distal thigh and advanced, often under ultrasound guidance, nearly to the saphenofemoral junction. The catheter is then slowly withdrawn while controlled radiofrequency or laser energy is applied. This is followed by external compression of the treated segment.

Doppler ultrasound or duplex studies are often used to map the anatomy of the venous system prior to the procedure. There is adequate evidence that pre-procedural ultrasound is helpful, and Medicare will cover one ultrasound or duplex scan prior to the procedure to determine the extent and configuration of the varicosities when it is medically necessary.

Evidence and clinical experience supports the use of ultrasound guidance during the procedure and shows that the outcomes may be improved and complication rates may be minimized when ultrasound guidance is used. The CPT codes for radiofrequency and laser include the intra-

operative ultrasound service in the valuation and ultrasound may not be billed separately with these procedures.

A duplex ultrasound examination is considered medically necessary and will be allowed when performed within 1 week (preferably within 72 hours) of EFRA to check for any evidence of thrombus extension from the saphenofemoral junction into the deep system.

A. Indications for surgical treatment and sclerotherapy:
1. A 3-month trial of conservative therapy such as exercise, periodic leg elevation, weight loss, compressive therapy, and avoidance of prolonged immobility where appropriate, has failed, AND
2. The patient is symptomatic and has one, or more, of the following:
   a. Pain, aching, cramping, burning, itching and/or swelling during activity or after prolonged standing 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
3. The treatment of spider veins/telangiectasis will be considered medically necessary only if there is associated hemorrhage.

B. Indications for ERFA or laser ablation:
In addition to the above (see A), the patient's anatomy and clinical condition are amenable to the proposed treatment including ALL of the following:
1. Absence of aneurysm in the target segment.
2. Maximum vein diameter of 20 mm for ERFA or 30 mm for laser ablation.
3. Absence of thrombosis or vein tortuosity, which would impair catheter advancement.
4. The absence of significant peripheral arterial diseases.

C. Limitations for ERFA and laser ablation:
1. ERFA and laser ablation are covered only for the treatment of symptomatic varicosities of the lesser or greater saphenous veins and their tributaries which have failed 3 months of conservative therapy.
2. Intra-operative ultrasound guidance is not separately payable with ERFA, laser ablation.
3. The treatment of asymptomatic varicose veins, or symptomatic varicose veins without a 3-month trial of conservative measures, by any technique, will be considered cosmetic and therefore not covered.
4. The treatment of spider veins or superficial telangiectasis by any technique is also considered cosmetic, and therefore not covered unless there is associated bleeding.
5. Coverage is only for devices specifically FDA-approved for these procedures.
6. One pre-operative Doppler ultrasound study or duplex scan will be covered.
7. Post –procedure Doppler ultrasound studies will be allowed if medically necessary.

The stab phlebectomy of the same vein performed on the same day as endovenous radiofrequency or laser ablation may be covered if the criteria for reasonable and necessary as described in this LCD are met. If sclerotherapy is used with endovenous ablation, it may be covered if the criteria for reasonable and necessary as described in this LCD are met.

The treatment of asymptomatic veins with endoluminal ablation or sclerotherapy is not considered medically reasonable and necessary. If it is determined on review that the varicose veins were asymptomatic, the claim will be denied as a noncovered (cosmetic) procedure.

These procedures are not directly addressed in the LCD. There is a Medicare fee schedule for codes 36473, 36474, 36482 and 36483.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Echosclerotherapy for the Treatment of Varicose Veins

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/17	2/21/17	2/21/17	Joint policy established
5/1/18	2/20/18	2/20/18	Updated background and rationale sections. Added codes 36482 and 36483 as E/I effective 12/1/18. Added references 12-15. Policy title changed. No change in policy status.
7/1/19	4/16/19		Routine policy maintenance. No change in policy status.
7/1/20	4/14/20		Status change to established for cyanoacrylate adhesive, MOCA remains E/I. Rationale reorganized, some references deleted, others added.
7/1/21	4/20/21		Routine policy maintenance, no changes in policy status.
7/1/22	5/9/22		Routine policy maintenance, no change in policy status. Clarifications made in MPS related to conservative therapy and compression garments.
7/1/23	4/18/23		Policy replaced with Treatment for Varicose Veins/Venous Insufficiency. (ds)

Next Review Date: Policy is replaced by JUMP policy, *Treatment for Varicose Veins/Venous Insufficiency.*

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ENDOVENOUS ABLATION FOR THE TREATMENT OF VARICOSE VEINS (E.G., CLARIVEIN®, VENASEAL™ CLOSURE SYSTEM)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Per policy
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.