New Century Health

Cardio Policy:

Endovascular Venous Laser/Radiofrequency Ablation

POLICY NUMBER UM CARDIO_1252	**SUBJECT** Endovascular Venous Laser/Radiofrequency Ablation	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 6**
DATES COMMITTEE REVIEWED 11/14/13, 12/17/13, 03/03/14, 02/19/15, 12/21/16, 10/11/17, 11/14/18, 02/13/19, 03/13/19, 05/08/19, 06/12/19, 12/11/19, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 04/13/22	**APPROVAL DATE** April 13, 2022	**EFFECTIVE DATE** April 29, 2022	**COMMITTEE APPROVAL DATES** 11/14/13, 12/17/13, 03/03/14, 02/19/15, 12/21/16, 10/11/17, 11/14/18, 02/13/19, 03/13/19, 05/08/19, 06/12/19, 12/11/19, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 04/13/22
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

Indications for determining medical necessity for Lower Extremity Endovenous Laser/Radiofrequency Ablation.

II. DEFINITIONS

Varicose veins are a manifestation of chronic venous disease (CVD) caused by ambulatory venous hypertension which are superficially located, dilated (> 3mm), tortuous, veins of the lower extremities. These dilated superficial veins of the lower limbs are considered pathologic when they are 5 mm or greater in diameter or sometimes 3 mm or greater in diameter when measured in the upright position and have greater than 500milliseconds of reflux by duplex scan.

Spider veins are intradermal venules of <1 mm, also known as telangiectasia or thread veins. Reticular veins are intradermal venules of 1-3 mm. Superficial veins are truncal (GSV/SSV) and accessory/tributary veins located nearest to the skin. Perforator veins are the veins linking the superficial and deep veins. Deep veins are located deep to the muscular fascia, such as the common femoral vein. These can cause clinically significant pain and result in a decrease in quality of life and even disability which may necessitate treatment.

The evaluation of a patient with lower extremity venous incompetence and its advanced consequences-edema and skin changes-should include the assessment of history and physical examination including the CEAP classification and revised Venous Clinical Severity Score (VCSS). A duplex ultrasound scan of the deep and superficial venous systems must support the examination findings.

Classification for chronic venous disorders (CVD and CVI) is based on clinical severity (C), etiology (E), anatomy (A), and pathophysiology (P) to improve the accuracy of the diagnosis.

C 0 – no visible or palpable signs of venous disease
C 1 – Telangiectasias or reticular veins less than 3 mm
C 2 – Simple varicose veins (3 or larger)
C 3 – Ankle edema of venous origin (not foot edema)
C 4a – Skin pigmentation or eczema
C 4b – Lipodermatosclerosis or atrophic blanche
C 5 – Healed venous ulcer
C 6 – Open venous ulcer

S – Symptomatic, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, and other complaints attributable to venous dysfunction

A – Asymptomatic

Etiologic

Classification:
Ec – Congenital
Ep – Primary
Es – Secondary (post-thrombotic)
En – No venous cause identified

Anatomic classification:
As – Superficial veins
Ap – Perforator veins
Ad – Deep veins
An – No venous location identified

Pathophysiologic classification:
Pr – Reflux
Po – Obstruction
Pr, o – Reflux and obstruction
Pn – No venous pathophysiology

Venous Clinical Severity Score:
Pain or other discomfort (i.e., aching, heaviness, fatigue, soreness, burning)
None=0: None
Mild=1: Occasional pain or discomfort that does not restrict daily activities
Moderate=2: Daily pain or discomfort that interferes with, but does not prevent, regular daily activities
Severe=3: Daily pain or discomfort that limits most regular daily activities

Varicose Veins
None=0: None

Mild=1: Few, scattered, varicosities that are confined to branch veins or clusters. Includes “corona phlebectatica” (ankle flare), defined as >5 blue telangiectasia at the inner or sometimes the outer edge of the foot
Moderate=2: Multiple varicosities that are confined to the calf or the thigh
Severe=3: Multiple varicosities that involve both the calf and the thigh

Venous Edema
None=0: None
Mild=1: Edema that is limited to the foot and ankle
Moderate=2: Edema that extends above the ankle but below the knee
Severe=3: Edema that extends to the knee or above

Skin Pigmentation
None=0: None, or focal pigmentation that is confined to the skin over varicose veins
Mild=1: Pigmentation that is limited to the peri-malleolar area
Moderate=2: Diffuse pigmentation that involves the lower third of the calf
Severe=3: Diffuse pigmentation that involves more than the lower third of the calf

Induration
None=0: None
Mild=1: Induration that is limited to the peri-malleolar area
Moderate=2: Induration that involves the lower third of the calf
Severe=3: Induration that involves more than the lower third of the calf

Active Ulcer Number
None=0: None
Mild=1: One Ulcer
Moderate=2: Two Ulcers
Severe=3: Three Ulcers

Active Ulcer
None=0: No active ulcers
Mild=1: Ulceration present for <3 months
Moderate=2: Ulceration present for 3-12 months
Severe=3: Ulceration present for >12 months

Active Ulcer Size
None=0: No active ulcer
Mild=1: Ulcer <2 cm in diameter
Moderate=2: Ulcer 2-6 cm in diameter
Severe=3: Ulcer >6 cm in diameter

Use of Compression Therapy based on compliance
None=0: Not used
Mild=1: Intermittent use
Moderate=2: Wears stockings most days
Severe=3: Full compliance stockings

Endovenous Radiofrequency Ablation is a minimally invasive endovenous thermal ablation procedure that involves using ultrasound guidance to puncture the vein, position a catheter and perform tumescent anesthesia. Radiofrequency current is delivered resulting in heat destruction while

an inflammatory response enhances wall destruction. The purpose of RFA is to damage the collagen of the vein wall resulting in fibrosis and occlusion of a vein segment to eliminate reflux. This procedure may be performed in the outpatient setting.

Endovenous Laser Ablation is a minimally invasive alternative to high ligation and saphenous vein stripping (HL/S). It is only a treatment option for sufficiently straight superficial vein segments that will allow passage of the device. The purpose of EVLA is to damage the endothelium of the vein resulting in fibrosis and occlusion of a vein segment to eliminate reflux. The thermal ablation techniques are appropriate for the primary treatment of the GSV and/or SSV, and incompetent accessory (AAGSV, PAGSV) saphenous veins.

Mechanochemical Ablation, also referred to as MOCA, MECA is a technique used to ablate superficial veins with an oscillating wire that rotates and disrupts the endothelial lining of target veins while a sclerosant is injected to penetrate the deep layers of the vein causing vein sclerosis. This technique is appropriate for the treatment of truncal veins.

The objective of Endovenous techniques is to cause injury to the vessel, causing retraction and subsequent fibrotic occlusion of the vein thereby eliminating reflux.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

All below indications are applicable only if there is documentation of failure of compression therapy for 90 days except in presence of non- healing ulcers.

A. Patients with C2 disease and VCSS score < 6, symptomatic GSV (≥ 5mm in size with ≥ 500ms in duration of reflux) and for SSV (≥ 3mm in size with ≥ 500ms in duration of reflux) endovenous laser and radiofrequency ablation(s). GSV and SSV ablation can be performed at the same time or staged. **(AUC Score 6)**[1,2,3,4,5,6]. Ablation of perforator vein(s) is not indicated during initial truncal (GSV/SSV) ablation, due to insufficient evidence in literature.

B. For patients with C2 disease and VCSS score > 6, endovenous laser and radiofrequency ablation(s) of symptomatic **GSV** (≥ 5mm in size with ≥ 500ms in duration of reflux), **Accessory/Tributaries** Saphenous Vein (≥ 3mm in size with duration of reflux ≥ 500ms) or **SSV** (≥ 3mm in size with ≥ 500ms in duration of reflux) can be performed. These veins can be performed at the same time or staged **(AUC Score 6)**[1,2,3,4,5,6]

C. For patients with C3-C6 disease, endovenous laser and radiofrequency ablation(s) of **GSV** (≥ 5mm in size with duration of reflux ≥ 500ms), **Accessory/Tributaries** Saphenous Vein (≥ 3mm in size with duration of reflux ≥ 500ms) or **SSV** (≥ 3mm in size with duration of reflux ≥ 500ms) can be performed. These veins can be performed at the same time or staged. **(AUC Score 8)**[1,2,3,4,5,6]

D. For patients with C3-C6 disease, Perforator veins(s) endovenous laser and radiofrequency ablation(s) requires below criteria to be met **(AUC Score 7)**[1,2,3,4,5,6]
    1. C3-C6 disease and,
    2. ≥ 3.5mm, duration of reflux ≥ 5500ms and,
    3. Refluxing isolated perforator vein(s) lies beneath or contiguous to a healed or active venous ulcer and/or
    4. At the same time of GSV/Accessory Saphenous/SSV ablation in presence of ulcer or,
    5. Perforator vein(s) ablation can be performed during a redo GSV/SSV intervention when criteria 1 and 2 are met, for the same leg at the same time.

E. Redo EVLA for GSV/SSC can be done only once every 3 years **(AUC Score 8)**[1,2,3,4,5,6]

F. Endovenous mechanochemical ablation of GSV (at least 5mm in size with duration of reflux ≥ 500ms) for patients with C3-C6 disease or C2 with VCSS <6 or C2 with VCSS <6, can be performed instead of Endovenous Laser or Radiofrequency ablation **(AUC Score 8)**[1,2,5,6]

G. Endo Chemical Venous Ablation also called as glue embolization can be performed for GSV (≥ 5mm in size with duration of reflux ≥ 500ms) and SSV (at least ≥ 3mm in size with duration of reflux ≥ 500ms)

A complete Venous Duplex after each venous intervention is preferred to demonstrate the result of intervention on the intervened vein(s) and to reassess presence of reflux on next target vein(s) of the same extremity.

Limitations:

A. This procedure cannot be performed in presence of aneurysm, thrombosis, or vein tortuosity in target segment or if maximum vein diameter ≥ 20mm.

B. Venous Insufficiency due to DVT is a contraindication for this procedure.

C. Repeated procedures for venous ablation performed more than twice, on the same area of the same vein, in separate surgical procedures, are considered not medically necessary.

D. The treatment of C1 disease (spider telangiectasia and their feeding reticular veins) is considered cosmetic, and therefore, will not be eligible for this treatment coverage except in patients with spontaneous and/or traumatic venous hemorrhage.

E. The treatment of CEAP clinical classification C0 (no visible or palpable signs of venous disease) is considered cosmetic, and therefore, not reasonable, and necessary for the purposes of Medicare coverage.

F. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
    1. Progress note that prompted the request
    2. Latest venous duplex report supporting request describing reflux (location and duration of reflux) and anatomy of veins with CEAP classification and VCSS score.
    3. Prior venous intervention report

B. Primary codes appropriate for this service: Endo Mechanochemical Ablation: 36473, 36474; Endovenous Radiofrequency Ablation: 36475, 36476, Endovenous Laser Ablation 36478, 36479; Endo Chemical Venous Ablation 36482, 36483.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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3. Neil M. Khilnani, et al. Multi-society Consensus Quality Improvement Guidelines for the Treatment of Lower- extremity Superficial Venous Insufficiency with Endovenous Thermal Ablation from the Society of Interventional Radiology, Cardiovascular Interventional Radiological Society of Europe, American College of Phlebology, and Canadian Interventional Radiology Association. Journal of Vascular and Interventional Radiology. January 2010. Volume 21, Issue 1, Pages 14-31.
4. Van Eekeren RR, et al. Endovenous mechanochemical ablation of great saphenous vein incompetence using the ClariVein device: a safety study. Journal of endovascular therapy: an official journal of the International Society of Endovascular Specialists. June 2011. Volume 18, Issue 3, Pages 328-34.
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6. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305- 1317.
7. NCQA UM 2022 Standards and Elements.