PROVIDER POLICIES & PROCEDURES

TREATMENT OF VARICOSE VEINS OF THE LOWER EXTREMITY - CYANOACRYLATE ADHESIVE

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for treatment of varicose veins of the lower extremities with cyanoacrylate adhesive (e.g., VenaSeal Closure System). By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Varicose veins are abnormally enlarged and tortuous vessels caused by incompetent valves in the venous system that allow blood leakage or reflux. They are an indication of an underlying syndrome of venous insufficiency. Venous insufficiency syndromes allow venous blood to escape from its normal flow path and flow into an already congested leg. The condition becomes clinically significant when symptoms such as cramping, throbbing, burning and swelling become pronounced. Severe varicosities may be associated with dermatitis, ulceration, and thrombophlebitis.

Conservative measures often yield satisfactory results in relieving symptoms that produce functional impairment. When these don't, however, a variety of invasive treatments are available. A significant number of individuals additionally seek treatment for cosmetic reasons.

Cyanoacrylate adhesive is a clear liquid that polymerizes in the vessel into a solid material on contact with body fluids or tissue. The adhesive is gradually injected along the length of the vein using ultrasound in conjunction with manual compression. The acute coaptation halts blood flow through the vein until the implanted adhesive becomes encapsulated and establishes permanent occlusion of the treated vein.

CLINICAL GUIDELINE

Coverage guidelines are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity. The following criteria are guidelines *only.* Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Treatment of Great or Small Saphenous Veins

Cyanoacrylate adhesive may be considered medically necessary for treatment of symptomatic varicose veins/venous insufficiency when the following criteria are met:

A. There is demonstrated saphenous reflux and CEAP [Clinical-Etiology-Anatomy-Pathophysiology] class C2 or greater;
   AND
B. There is documentation of **ONE or more** of the following indications:

- Venous stasis ulcers
- Recurrent superficial thrombophlebitis
- Hemorrhage or recurrent bleeding episodes from a superficial varicosity
- Persistent pain, swelling, itching, burning at the affected area **and**:
    - These symptoms significantly interfere with activities of daily living; **and**
    - There is documentation of conservative management (including compression therapy*) for at least 3 months that has not improved these symptoms. If compression therapy is contraindicated, documentation describing the contraindication is required.

Treatment of Accessory Saphenous Veins

Cyanoacrylate adhesive may be considered medically necessary for treatment of symptomatic accessory saphenous veins/venous insufficiency when the following criteria are met:

A. Incompetence of the accessory saphenous vein is isolated or the great or small saphenous veins had been previously eliminated (at least 3 months);
   AND
B. Documented accessory saphenous reflux;
   AND
C. There is documentation of **ONE or more** of the following indications:
    - Venous stasis ulcers
    - Recurrent superficial thrombophlebitis
    - Hemorrhage or recurrent bleeding episodes from a superficial varicosity
    - Persistent pain, swelling, itching, burning at the affected area **and**:
        - These symptoms significantly interfere with activities of daily living; **and**
        - There is documentation of conservative management (including compression therapy*) for at least 3 months that has not improved these symptoms. If compression therapy is contraindicated, documentation describing the contraindication is required.

*Compression therapy is the use of surgical grade compression hose (minimum 20-30 mm Hg) that have been prescribed by a physician with the trial use documented in the medical record.

Not Medically Necessary

Treatment of telangiectasia such as spider veins, angiomata, and hemangiomata is considered cosmetic and not medically necessary.

NOTE: EPSDT Special Provision

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Prior authorization for treatment of varicose veins of the lower extremities with cyanoacrylate adhesive is

required. Requests will be reviewed in accordance with procedures in place for reviewing requests for surgical procedures. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for these treatments:

- Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal
- Specific vein(s)/leg(s) to be treated
- Results of duplex ultrasonography
- CEAP class
- Documentation from the requesting physician which includes:
    - History and physical examination with description of varicose vein(s)
    - Operative notes from primary procedure (i.e., ligation and stripping, endovenous ablation etc.), if applicable
    - Modalities used to manage the condition conservatively or documentation supporting the individual's inability to fully participate in conservative management
    - Current symptoms
    - Functional impairment

Note: Photographs may be requested.

EFFECTIVE DATE

This Policy is effective for prior authorization requests for varicose vein treatments for individuals covered under the HUSKY Health Program beginning May 1, 2021.

LIMITATIONS

N/A

CODES:

36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

DEFINITIONS

1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.

2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

- Almeida JI, Javier JJ, Mackay E, Bautista C, Proebstle TM. First human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. J Vasc Surg Venous Lymphat Disord. 2013;1(2):174-180. doi:10.1016/j.jvsv.2012.09.010

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- Gibson K, Ferris B. Cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of post-procedure compression: Initial outcomes of a post-market evaluation of the VenaSeal System (the WAVES Study). Vascular. 2017;25(2):149-156. doi:10.1177/1708538116651014
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- Morrison N, Gibson K, McEnroe S, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). J Vasc Surg. 2015;61(4):985-994. doi:10.1016/j.jvs.2014.11.071
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- Proebstle TM, Alm J, Dimitri S, et al. The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins. *J Vasc Surg Venous Lymphat Disord*. 2015;3(1):2-7. doi:10.1016/j.jvsv.2014.09.001
- UptoDate. Liquid, foam and glue Sclerotherapy techniques for the treatment of lower extremity veins. Last updated December 2, 2019.
- U.S. Food and Drug Administration. VenaSeal Closure System. PMA P140018. 2015. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140018 Accessed on February 25, 2021.

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PUBLICATION HISTORY

Status	Date	Action Taken
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