

FINAL Key Questions and Background

Selected Endovascular and Surgical Interventions for Treating Varicose Veins

Varicose veins are a common condition, affecting approximately 25 million people in the United States. The National Heart, Lung, and Blood Institute provides the following information about varicose veins. Varicose veins are swollen, twisted veins visible under the surface of the skin. Veins have one-way valves that help keep blood flowing toward the heart. If the valves are weak or damaged, blood can back up and pool in veins. This causes the veins to swell, which can lead to varicose veins. These veins usually occur in the legs, but can also form in other parts of the body.

Many factors can raise a person's risk for varicose veins. Examples of these factors include family history, older age, gender, pregnancy, overweight or obesity, lack of movement, and leg trauma.

Sometimes varicose veins cause pain, blood clots, skin ulcers, or other problems. Varicose veins can lead to dermatitis. Dermatitis can cause bleeding or skin ulcers if the skin is scratched or irritated. Varicose veins also can lead to a condition called superficial thrombophlebitis, a blood clot in a vein close to the surface of the skin. This type of blood clot may cause pain and other problems in the affected area.

Varicose veins are treated with lifestyle changes and medical procedures. The goals of treatment are to relieve symptoms, prevent complications, and improve appearance. Medical procedures are done either to remove varicose veins or to close them. Examples of medical procedures are:

- Sclerotherapy: Injection of a liquid (or foam) chemical to close off a varicose vein
- Endovenous ablation: Lasers or radiowaves to create heat to close off a varicose vein
- Ambulatory phlebectomy: Small cuts in the skin to remove small varicose veins
- Vein stripping and ligation: Tying shut and removing veins through small cuts in the skin

Policy Context

A variety of treatments for varicose veins are available. Treatment goals include reducing pain or discomfort and for cosmetic reasons. The topic is identified based on uncertainties related to the safety, efficacy, and value of the certain procedures, including chemical ablation, stab phlebectomy, and laser ablation.

Scope of This HTA

Population: Adult patients being treated for varicose veins.

Interventions: Endovascular laser ablation (EVLA), endovascular radiofrequency ablation (RFA), sclerotherapy (i.e., liquid or foam chemical ablation), ambulatory phlebectomy (i.e., stab phlebectomy or microphlebectomy)

Comparators: Any of the interventions listed above compared with vein ligation with or without stripping

Outcomes:

- Clinical outcomes: Failure of the procedure, second or additional procedures after failure of initial procedure, technical recurrence, symptomatic recurrence, second or additional procedures to treat recurrence, changes in symptom scores measured by validated scales (e.g., Venous Clinical Severity Score [VCSS])
- Patient-centered outcomes: Patient satisfaction/quality of life (QOL); time to return to work or normal activity; pain
- Adverse events: Nerve damage, skin burns, deep venous thermal injury, deep vein thrombosis, pulmonary embolism, transient ischemic attacks, stroke, bleeding, infection, thrombophlebitis, headache, visual disturbance, skin staining, pain at injection site, back pain, anaphylaxis, lymph leak, cellulitis
- Cost/cost-effectiveness outcomes

Settings: Inpatient or outpatient

Study Designs: For clinical effectiveness (key questions 1 and 3), good-quality systematic reviews and randomized controlled trials (RCTs); for harms (key questions 2 and 3) in addition to good-quality systematic reviews and RCTs, large observational studies including registry data (n≥500), may be employed; similarly, for key question 4, observational and modelling studies may be also be employed.

Key Questions

1. Among patients being treated for varicose veins, what is the clinical effectiveness of endovascular laser ablation, radiofrequency ablation, sclerotherapy, or ambulatory phlebectomy compared with ligation with or without stripping?
2. Among patients being treated for varicose veins, what are the harms associated with endovascular laser ablation, radiofrequency ablation, sclerotherapy, or ambulatory phlebectomy compared with ligation with or without stripping?
3. Among patients being treated for varicose veins, does the effectiveness or risk of adverse events of laser ablation, radiofrequency ablation, sclerotherapy, or ambulatory phlebectomy compared with ligation with or without stripping vary by clinical history (e.g., comorbidities, previous treatment of varicose veins), patient characteristics (e.g., age, sex, body mass index (BMI), smoking history)?
4. What are the cost implications and cost-effectiveness of endovascular laser ablation, radiofrequency ablation, sclerotherapy, or ambulatory phlebectomy compared with ligation with or without stripping for patients being treated for varicose veins?

Public Comment & Response

See **Draft Key Questions: Public Comment and Response** document published separately.