



## Voting Question 1 & Responses:

**MEDCAC Question 1:** *For adults with varicose veins and/or other clinical symptoms or signs of chronic venous insufficiency, how confident are you that there is sufficient evidence for an intervention that improves:*

- a.** *Immediate/near-term health outcomes in patients presenting with symptoms?*

**Hamilton Vein Center Response: 5**

*In patients presenting without symptoms but with physical signs?*

**Hamilton Vein Center Response: 4**

- b.** *Long-term health outcomes in patients presenting with symptoms?*

**Hamilton Vein Center Response: 5**

*In patients presenting without symptoms but with signs?*

**Hamilton Vein Center Response: 5**

### **MEDCAC Discussion:**

- *If intermediate confidence ( $\geq 2.5$ ), please identify the specific intervention(s) that are associated with evidence-based clinical benefit and identify the associated beneficial outcome(s).*
- *Considering the heterogeneity of the Medicare population, discuss for which subgroups of the Medicare population the evidence demonstrates likely benefit or which subgroups are not likely to benefit from intervention.*

### **Hamilton Vein Center Response:**

In the United States, an estimated 23% of adults have varicose veins, and 6% have more advanced chronic venous disease (CVD), including skin changes and healed or active venous ulcers. Varicose veins often cause discomfort, pain, loss of working days, disability, and deterioration of health-related quality of life (QOL). Severe CVD may also lead to loss of limb or loss of life.

According to the *Clinical Practice Guidelines of the Society of Vascular Surgery and the American Venous Forum*, the prevalence of varicose veins in the adult western population is 20% and about



5% have venous edema, skin changes or venous ulcerations. Active venous ulcers are present in up to 0.5% of the adult western population and between 0.6% and 1.4% of that population have healed ulcers. The San Diego epidemiologic study estimates that, more than 11 million men and 22 million women between the ages of 40 and 80 years in the United States have varicose veins, and 2 million adults have advanced CVD, with skin changes or ulcers.

In the North American Subfascial Endoscopic Perforator Surgery (SEPS) Registry, more patients with advanced chronic venous insufficiency had primary venous disease than post-thrombotic syndrome (70% vs 30%) demonstrating that primary varicosities can progress to severe CVI and venous ulcer formation.

Varicose veins and associated complications may lead to chronic pain, disability, decreased quality of life (QOL), loss of employment days, and even early retirement. In the United States, the direct medical cost of CVD is estimated to be between \$150 million and \$1 billion annually.

Compression therapy has been shown to be an effective non-intervention method for the management of symptoms related to superficial disease for a certain subgroup of patients, but compression therapy does nothing to correct the underlying source of reflux. If patients have a correctable source of reflux defined as  $\geq 500$ ms, definitive intervention treatment should be offered, unless it is contraindicated or unwanted.

The *American College of Phlebology Practice Guidelines for the Treatment of Superficial Venous Disease of the Lower Leg* recommends against compression therapy as a prerequisite therapy for symptomatic venous reflux disease when other definitive treatments such as endovenous ablation are appropriate. This is a GRADE 1A recommendation.

In general, indications for treatment include symptoms: pain, aching, heaviness, fatigue, soreness, burning, varix hemorrhage, recurrent superficial phlebitis. Signs include: edema, venous stasis dermatitis, lipodermatosclerosis and ulceration. Both the *American College of Phlebology Practice Guidelines for the Treatment of Superficial Venous Disease* and the *Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum* recommend using the CEAP classification (don't assume that the readers will understand CEAP classifications, you should describe what the CEAP classification is) for patients with chronic venous disease. Furthermore, the American College of Phlebology Practice Guidelines state medical necessity as a CEAP classification of C2 or higher. This is a GRADE 1A recommendation.

Endovenous thermal ablation (laser and radiofrequency) is the preferred treatment for saphenous and accessory saphenous (GSV, SSV, AAGSV, PAGSV) vein incompetence, again defined as reflux  $\geq 500$ ms GRADE 1B. Endovenous thermal ablation is recommended over open surgery due to reduced convalescence and less pain and morbidity.



Consensus guidelines recommend varicose (visible) symptomatic tributary veins can be treated by either stab phlebectomy, liquid sclerotherapy or foam chemical ablation. This is based on GRADE 1B evidence according to the American College of Phlebology Practice Guidelines for the treatment of superficial venous disease of the lower leg. They further recommend (non visible) symptomatic tributary veins be treated by ultrasound guided liquid sclerotherapy or foam chemical ablation with GRADE 1B evidence.

According to consensus guidelines treatment of incompetent perforating veins located beneath a healed or open venous ulcer is recommended (C5 or C6). Perforators should have refluxing flow of  $\geq 500$  ms, with a diameter of  $\geq 3.5$  mm. These are considered “pathologic perforating veins.” This is based on GRADE 2B evidence according to both guidelines.

In patients with perforator reflux as the primary or only source of disease, treatment of the perforator is recommended with endovenous thermal ablation, ligation or ultrasound guided sclerotherapy. Subsequent or simultaneous treatment of symptomatic varicosities arising from the incompetent perforator is also considered best practice. This is GRADE 2B evidence.

Consensus recommendation recommends the use of the revised Venous Clinical Severity Score for assessment of clinical outcome after therapy for varicose veins and more advanced chronic venous disorders. This is GRADE 1B evidence.

#### References:

- *The American College of Phlebology Practice Guidelines for the Treatment of Superficial Venous Disease*
- *Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML, Lohr JM, McLafferty RB, Meissner MH, Murad MH, Padberg FT, Pappas PJ, Passman MA, Raffetto JD, Vasquez MA, Wakefield TW. The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg 2011 Volume 53, Issue 5, Supplement, Pages 2S-48S*



## Voting Question 2 & Responses:

**MEDCAC Question 2:** *For adults with chronic venous thrombosis and venous obstruction (including individuals with post-thrombotic syndrome), how confident are you that there is sufficient evidence for an intervention that improves:*

- a. Immediate/near-term health outcomes in patients presenting with symptoms?*

**Hamilton Vein Center Response: 5**

*In patients presenting without symptoms but with signs?*

**Hamilton Vein Center Response: 4**

- b. Long-term health outcomes in patients presenting with symptoms?*

**Hamilton Vein Center Response: 4**

*In patients presenting without symptoms but with signs?*

**Hamilton Vein Center Response: 4**

### **MEDCAC Discussion:**

- If intermediate confidence ( $\geq 2.5$ ), please identify the specific intervention(s) that are associated with evidence-based clinical benefit and identify the associated beneficial outcome(s).*
- Considering the heterogeneity of the Medicare population, discuss for which subgroups of the Medicare population the evidence demonstrates likely benefit or which subgroups are not likely to benefit from intervention.*

- a. Immediate/near-term health outcomes?*

- b. Long-term health outcomes?*

### **Hamilton Vein Center Response:**

Regarding the intervention for adults with chronic venous thrombosis and venous obstruction the American College of Phlebology Practice Guidelines for Chronic Deep Venous Obstruction: Recommendations for the Management of Obstruction of the Femoroiliocaval Venous System are:

- 1. We recommend venous balloon angioplasty and stenting for treatment of non-thrombotic and post-thrombotic iliac and common femoral venous obstructions in patients with lower extremity*



*pain or edema affecting QOL not palliated by compression and for patients with impending or active lower extremity venous leg ulceration. Grade 1B*

*2. We recommend venous balloon angioplasty and stenting for treatment of non-thrombotic and post-thrombotic IVC obstructions in patients with lower extremity pain or edema affecting QOL not palliated by compression and for patients with impending or active lower extremity venous leg ulceration. Grade 1C*

*3. We recommend venous balloon angioplasty and stenting for treatment of non-thrombotic and post-thrombotic iliac venous obstructions in patients with chronic pelvic pain, deep dyspareunia, or low back pain which severely affect the QOL when other likely causes have been excluded and the severity of the iliac vein obstruction is considered sufficient to explain the symptoms. Grade 1C*

In Gloviczki P, *Handbook of Venous Disorders: Guidelines of the American Venous Forum* Guideline 4.17.0 gives a Grade 1 recommendation (we recommend) for endovenous stenting to improve symptoms and QOL for patients with chronic iliofemoral obstruction and the Grade of evidence is rated A (high quality). Guideline 4.18.0 gives a Grade 2 recommendation (we suggest) for endovascular stenting for reconstruction of complex ilio caval venous occlusions and the Grade of evidence is rated B (moderate quality). O'Donnell, et al., published in 2014 clinical practice guidelines of the Society of Vascular Surgery and the American Venous Forum for management of venous leg ulcers. This extensive review recommends balloon angioplasty/stenting of obstructed iliofemoral venous outflow in patients with venous leg ulcers.

Additional society guidelines exist which also support the use of BA and stenting for symptomatic venous obstructions:

2006-Society of Interventional Radiology Quality Improvement Guidelines

2006-Society of Interventional Radiology Position Statement

2011-American Heart Association Scientific Statement

2012-Society for Vascular Surgery and American Venous Forum

2014-American Heart Association Scientific Statement

#### References:

- *American College of Phlebology Practice Guidelines for Chronic Deep Venous Obstruction: Recommendations for the Management of Obstruction of the Femoroiliocaval Venous System*
- *Gloviczki P, Handbook of Venous Disorders: Guidelines of the American Venous Forum, 3rd ed., London: Edward Arnold, 2009*



## Additional Discussion Topics & Responses

3. *Discuss important venous disease evidence gaps that have not been previously or sufficiently addressed.*
4. *Discuss any current venous disease treatment disparities and how they may affect the health outcomes of Medicare beneficiaries.*
5. *Discuss any mechanisms that might be supported by CMS that would more quickly generate an improved evidence base that would underpin improved care for the Medicare population affected by lower extremity chronic venous diseases.*

### **Hamilton Vein Center Response:**

An important venous disease evidence gap is the role for treatment of pathologic perforator veins in patients with CEAP classification C4 in order to prevent possible progression to C5/C6.

Another is the role of Pelvic venography and treatment of pelvic vein, primarily iliac vein occlusion in patients with advanced chronic venous disease.

The ATTRACT Study, which has now completed enrollment is an NIH-funded, Phase III, multicenter, randomized, assessor-blinded, controlled clinical trial will hopefully shed light on the best way to treat patients with proximal DVT either with or without Pharmacomechanical Catheter-Directed Thrombolysis (PCDT). Specifically, the ATTRACT Study looks at the following questions: 1. Does PCDT prevent the Post-Thrombotic Syndrome? 2. Does PCDT Improve Quality of Life? 3. Is PCDT Safe Enough? 4. Is PCDT Cost-Effective? 5. What is the mechanism by which PCDT Prevents Post-Thrombotic Syndrome?

Unfortunately, because of significant variations in local coverage determinations (LCD), patients with varicose veins and other clinical symptoms or signs of chronic venous insufficiency in certain geographic areas of the country are being denied needed care and forced to delay treatment. Hamilton Vein Center believes that there should be a national coverage determination (NCD) with respect to treatment of varicose veins and that necessary treatment should not be denied or delayed for patients based on an LCD.

The research referenced in these comments and the results of the ATTRACT Study and other studies should be useful in establishing an NCD and assuring that all patients receive appropriate care and that no patient is denied care based on where the patient lives.

If you have any questions or need additional information, please let us know. Thank you for the opportunity to comment on varicose vein treatment interventions.