

Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)
Lower Extremity Chronic Venous Disease
July 20, 2016

This MEDCAC meeting will examine the scientific evidence underpinning the benefit and risk of existing lower extremity chronic venous disease interventions that aim to improve health outcomes in the Medicare population. This meeting will also identify evidence gaps that exist related to lower extremity chronic venous disease. Lower extremity chronic venous disease is distinct from lower extremity peripheral artery disease as it is characterized by a different pathophysiology, epidemiology, set of clinical manifestations, and outcomes. Lower extremity chronic venous disease includes heterogeneous disorders that encompasses a variety of primary etiologies. Nevertheless, common to most of these venous conditions is a permanent alteration in venous structure and function, which leads to altered venous hemodynamics.

Causes of altered venous blood flow include venous dilation and venous valvular reflux (venous valvular incompetence or “chronic venous insufficiency”) or venous obstruction (from prior venous thrombosis or mechanical compression). Patients with any of these venous structural alterations may be asymptomatic or symptomatic, suffering from mild pain to severe discomfort, with or without edema. Chronic venous disease can lead to major decrements in quality of life, and be associated with quality-of-life altering physical stigmata, including telangiectasias and varicose veins. Venous obstruction, venous insufficiency, and post-thrombotic syndrome patients may suffer from significant dependent edema and loss of ambulatory function. When venous insufficiency is associated with untreated (sustained) venous hypertension, the skin may be permanently damaged with initial and recurrent skin ulceration.

Existing therapies to improve outcomes for individuals with lower extremity chronic venous disease are grouped into four main categories: medical therapy, lifestyle interventions (including exercise, smoking cessation, and weight reduction), mechanical compression therapies (support garments, bandaging and pneumatic compressive devices), and invasive procedures (endovascular techniques including venous angioplasty, stenting and ablation; and surgical interventions, including venous thrombectomy, venous bypass, venous ligation, and venous excision).

Clinical outcomes of interest to the Medicare program include: reduction in pain; reduction in edema; improvement in functional capacity; improvement in quality of life; avoidance of acute and chronic venous thromboembolism; avoidance of chronic thromboembolic pulmonary hypertension; avoidance of initial venous skin ulceration and recurrent ulceration; improvement in wound healing; reduction in all-cause mortality; and avoidance of repeat interventions and harms from the interventions.

Voting Questions

For each voting question, please use the following scale identifying your level of confidence - with a score of 1 being low or no confidence and 5 representing high confidence.

<i>1</i> <i>Low</i> <i>Confidence</i>	<i>2</i>	<i>3</i> <i>Intermediate</i>	<i>4</i>	<i>5</i> <i>High</i> <i>Confidence</i>
---	----------	---------------------------------	----------	--

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? In patients presenting without symptoms but with physical signs?
 - b. Long-term health outcomes in patients presenting with symptoms? In patients presenting without symptoms but with signs?

Discussion:

- If intermediate confidence (≥ 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.
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? In patients presenting without symptoms but with signs?
 - b. Long-term health outcomes in patients presenting with symptoms? In patients presenting without symptoms but with signs?

Discussion:

- If intermediate confidence (≥ 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?

Additional Discussion Topics

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.

Table 1. Definitions of Terms

Term	Definition
Venous obstruction	Defined as partial or complete blockage of venous flow in any venous segment; can result from internal blockage (e.g., thrombosis) or external compression of the vein
Venous reflux	Used to describe any retrograde venous flow in any venous segment; typically classified as (a) primary/idiopathic, (b) secondary (typically due to trauma, thrombosis, or mechanical/chemical/thermal etiologies), or (c) congenital
Venous thrombosis	Defined as the formation of a blood clot in any segment of the venous system; typically classified as deep or superficial
Chronic venous insufficiency or incompetence (CVI)	Reserved for advanced venous disease, indicated by C3-C6 on the CEAP classification, and defined as morphological abnormalities of the venous system that lead to symptoms/signs (specifically, moderate-severe LE edema, skin changes, and/or venous ulcers)
Post-thrombotic syndrome	Describes chronic venous symptoms and/or signs that occur as a result of DVT and its sequelae

Abbreviations:

CEAP = Clinical, Etiologic, Anatomic, Pathophysiologic

DVT = deep vein thrombosis

LE = lower extremity