Report of the Society for Vascular Surgery and the American Venous Forum on the July 20, 2016 meeting of the Medicare Evidence Development and Coverage Advisory Committee panel on lower extremity chronic venous disease

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ABSTRACT

On July 20, 2016, a Medicare Evidence Development and Coverage Advisory Committee panel assessed the benefits and risks of currently used lower extremity chronic venous disease (CVD) treatments and their effects on health outcome of the American adult population. The main purpose of the meeting was to advise the Centers for Medicare & Medicaid Services on coverage determination for interventions used for treatment of CVD. A systematic review of the Agency for Healthcare Research and Quality was presented, followed by lectures of invited experts and a public hearing of

Key questions	Outcome in patients with and without symptoms	Level of confidence	
		MEDCAC	SVS/AVF
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?	3.3	4.0
	In patients presenting without symptoms but with physical signs?	2.0	1.0
	b. Long-term health outcomes in patients presenting with symptoms?	2.56	4.0
	In patients presenting without symptoms but with signs?	1.33	2
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?	2.11	3.00
	In patients presenting without symptoms but with signs?	1.44	2.00
	b. Long-term health outcomes in patients presenting with symptoms?	1.56	3.00
	In patients presenting without symptoms but with signs?	1.22	2.00

AVF, American Venous Forum; *MEDCAC*, Medicare Evidence Development and Coverage Advisory Committee; *SVS*, Society for Vascular Surgery.
Level of confidence: 1, low; 3, intermediate; 5, high.

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Presented at the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Meeting on Lower Extremity Venous Disease, Baltimore, Md, July 20, 2016.

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representatives of professional societies and the industry. After discussing critical issues, the panel voted for key questions. This report summarizes the presented evidence to support recommendations of the Society for Vascular Surgery/American Venous Forum coalition and the presentations on selected discussion topics. These included important venous disease evidence gaps that have not been sufficiently addressed, venous disease treatment disparities and how they may affect the health outcomes of Medicare beneficiaries, and mechanisms that might be supported by the Centers for Medicare & Medicaid Services to improve the evidence base to optimize the care of patients with lower extremity CVD. (J Vasc Surg: Venous and Lym Dis 2017;5:378-98.)

On July 20, 2016, the Centers for Medicare & Medicaid Services (CMS) convened a panel of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in Baltimore, Maryland.[1] The panel examined the scientific evidence supporting the benefits and risks of currently used lower extremity chronic venous disease (CVD) treatments and made recommendations to CMS by voting on the effects of these treatments on health outcome of the Medicare population.

THE MEDCAC PANEL

Composition of the panel. The panel was chaired by Rita Redberg, MD, Professor of Medicine, a cardiologist at the University of California, San Francisco, School of Medicine, and the nine-member voting panel included one venous disease expert physician, Peter F. Lawrence, MD, a vascular surgeon. The full composition of the voting panel was published on the CMS website.[1] There were two additional invited nonvoting guest panel members who were venous disease expert physicians: Anthony J. Comerota, MD, a vascular surgeon; and Teresa L. Carman, MD, a vascular medicine physician. There was also a nonvoting industry representative member on the panel.

Purpose of the meeting. The main purpose of the MEDCAC was to advise CMS as to whether the quality of the evidence was sufficient to be used by CMS in order to make a coverage determination for interventions used for treatment of CVD. Additional goals were to recognize evidence gaps and current venous disease treatment disparities and how they may affect health outcomes in Medicare beneficiaries. In addition, the panel was asked to identify mechanisms that might be supported by CMS that would more quickly generate an improved evidence base to better evaluate outcomes of current treatments of CVD in the adult population.[1]

Measurements of clinical outcome. Clinical outcomes of interest after treatment of CVD included the following: reduction in pain and edema; improvement in functional capacity and in quality of life (QoL); avoidance of acute and chronic venous thromboembolism; avoidance of chronic thromboembolic pulmonary hypertension; avoidance of venous skin ulcers and recurrent ulceration; improvement in wound healing; reduction in all-cause mortality; and avoidance of repeated interventions and harms from the interventions.[1]

Instructions to the panel and to experts and discussants who participated in the meeting suggested grouping of existing therapies into four 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 ablations; and surgical interventions, including venous thrombectomy, venous bypass, venous ligation/stripping, and venous excision).

Terminology. To unify terminology in the presentations and discussions, a definition of terms of CVD was provided by CMS (Table I).[1]

Presentations. The meeting included a detailed presentation of an Agency for Healthcare Research and Quality systematic review of evidence on treatment strategies for patients with chronic lower extremity venous disease, presented by Drs Schuyler Jones and Sreekanth Vemulapalli from Duke University Medical Center. This review was commissioned by CMS as part of preparation for the MEDCAC meeting. CMS recommended that the contents and conclusions of this analysis form an important basis for discussion and conclusions of the MEDCAC panel. The review was followed by invited presentations of venous disease experts, Thomas W. Wakefield, MD, and Fedor Lurie, MD, and by a public hearing. The scheduled 4-minute presentations were delivered by members of the Society for Vascular Surgery (SVS)/American Venous Forum (AVF) coalition and by members of the multiple society MEDCAC coalition that included the following societies: American College of Phlebology, Society for Interventional Radiology, American College of Cardiology, American College of Radiology, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, Alliance of Wound Care Stakeholders, and VIVA Physicians (Vascular Interventional Advances). Additional presentations were given by representatives of the Association for the Advancement of Wound Care, the International Union of Phlebology, and other societies and the AdvaMed industry coalition (Medtronic, Vascular Insights, Boston Scientific, C. R. Bard, and AngioDynamics).

The presentations were followed by discussion on early, midterm, and late outcomes of current treatments of CVD. Discussions of the voting questions were directed to identify specific interventions that are associated with evidence-based clinical benefit and to identify the associated beneficial outcomes. The panel asked