ORIGINAL ARTICLE

Vascular Specialist Response to Medicare Evidence Development Coverage Advisory Committee (MEDCAC) Panel on Peripheral Artery Disease of the Lower Extremities

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INTRODUCTION

On July 22, 2015 in Baltimore, Maryland, the Centers for Medicare and Medicaid Services (CMS) convened a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) panel to focus on lower extremity peripheral artery disease (PAD). The goal was to examine the scientific evidence of currently employed interventions that aim to improve health outcomes in the Medicare population, and address areas where evidence gaps may exist (https://www.cms.gov). The recommendations from this committee will then be considered by CMS as the basis for any future determinations about Medicare coverage for any interventions related to PAD. Therefore, the impact of this committee's advice to CMS may affect millions of Americans over the age of 65 years with PAD [1].

The MEDCAC committee considered the impact of three categorical non-mutually exclusive interventions, namely medical therapy, exercise training, and revascularization (endovascular or surgical) on asymptomatic patients with PAD; patients with intermittent claudication; or those with critical limb ischemia. The intermediate/near-term and long-term outcomes of interest were reduction in pain; avoidance of amputation; improvement in quality of life and/or functional capacity including walking distance; wound healing; avoidance of cardiovascular events (including myocardial infarction, stroke, cardiovascular death) and all-cause mortality; and avoidance of harm from the specific interventions. Furthermore, for each condition, panel members rated (on a scale of 1 to 5) the degree of confidence they had that a particular intervention impacted the outcome/s of interest. The results were averaged. Therefore, a total of six averaged scores were provided.

Given the potential impact of MEDCAC panel recommendations on the health of patients over the

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age of 65 who suffer from PAD, a coalition of seven not-for-profit organizations — including the American College of Radiology (ACR), American College of Cardiology (ACC), American Heart Association (AHA), The Society for Cardiovascular Angiography and Interventions (SCAI), Society of Interventional Radiology (SIR), Society for Vascular Medicine (SVM), and Vascular InterVentional Advances (VIVA) — was formed. Collaboratively, the coalition represented more than 150,000 members who routinely manage patients with PAD. This cooperative effort was unprecedented, and reflects the commitment of the member organizations to their patients who suffer from PAD.

Here we summarize the comments and responses to panel questions made by members of this Coalition during the MEDCAC panel meeting (Table 1).

ASYMPTOMATIC PAD

The association between PAD and cardiovascular morbidity and mortality is well known; however, the majority of patients with PAD remain unrecognized or undiagnosed [1]. Importantly, most of these patients are over the age of 65 years [2,3]. Indeed, history and physical examination have significant limitations in identifying those individuals with PAD, as the majority have atypical symptoms or are considered asymptomatic [4]. This has significant public health implications since PAD is considered a coronary artery disease risk equivalent, and, if unrecognized, carries significant morbidity and mortality [5]. Even those patients with asymptomatic PAD tend to have shorter 6-minute walk test results and poorer functional status [6]. Furthermore, timely diagnosis of PAD may lead to aggressive risk factor intervention as recommended by the AHA/ACC guidelines, and potentially result in a lower incidence of adverse cardiovascular and limb events. Data from the National Health and Nutrition Survey suggests that most patients remain undiscovered, are not treated with standard risk reduction medications, and the absence of appropriate medical therapy increases mortality significantly [7].

Once PAD has been identified, appropriate attention to anti-platelet therapy, lipid lowering, blood pressure control, smoking cessation, exercise, and diet modification should be given (ACC/AHA guidelines) [5]. Indeed, the Coalition noted that the ankle brachial index (ABI), the test used to identify PAD, should be reclassified by CMS, based on CMS criteria, as a diagnostic test to permit patient identification and treatment. In contrast, the Coalition found no benefit for routine supervised exercise training or any form of revascularization in patients with asymptomatic PAD.

INTERMITTENT CLAUDICATION

Intermittent claudication, the symptomatic form of PAD, is associated with reductions in in longevity and functional capacity. A number of medical therapies, including lifestyle modification, cigarette cessation, statin therapy, anti-platelet therapy, and blood pressure control, have been shown to reduce cardiovascular morbidity and mortality in patients with PAD; these have been

Table 1. Recommendations of the Coalition to MEDCAC questions according to condition, categorical interventions, and immediate or long-term outcomes*

Conditions	Categorical Intervention	Recommendation	
		Immediate/near-term	Long-term
Asymptomatic			
	Medical Therapy	Intermediate	High Confidence
	Exercise Training†	Intermediate	Intermediate
	Intervention	Low Confidence	Low Confidence
Intermittent Claudication			
	Medical Therapy	High Confidence	High Confidence
	Exercise Training	High Confidence	Intermediate
	Intervention‡	High Confidence	Intermediate
Critical Limb Ischemia			
	Medical Therapy	High Confidence	High Confidence
	Exercise Training	Intermediate	Intermediate
	Intervention	High Confidence	High Confidence

*Scored according to the recommendation by CMS and MEDCAC as low confidence, intermediate, or high confidence.
†Any form of exercise therapy to prevent cardiovascular outcomes.
‡Only after failed attempt at medical therapy, lifestyle modification and supervised exercise training and in conjunction with those.