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March 31, 2017

Tamara Syrek Jensen, JD  
Director  
Coverage and Analysis Group  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

RE: Proposed National Coverage Decision (NCD) Memorandum for Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (CAG-00449N)

Dear Ms. Syrek Jensen:

The American College of Cardiology (ACC), American College of Radiology (ACR), American Heart Association (AHA), Society for Cardiovascular Angiography and Interventions (SCAI), Society for Vascular Medicine (SVM), Society for Vascular Surgery (SVS), Society of Interventional Radiology (SIR), and VIVA Physicians appreciate this opportunity to comment on the proposed NCD. **The organizations applaud CMS for the decision to propose coverage for SET and offer several suggested revisions that would increase the likelihood SET is available to patients whom it will benefit.**

As CMS is aware, PAD is associated with pain, reduced quality of life, and reduced participation in both the workforce and normal daily activities. SET has been noted to improve pain-free walking, maximum walking time, maximum walking distance, and quality of life in meta-analysis,<sup>1</sup> a technical report,<sup>2</sup> and societal guidelines.<sup>3</sup>

<sup>1</sup> Nicolai SP, Hendricks EJ, Prins MH, et al. Exercise Therapy in Peripheral Arterial Disease (EXITPAD) study group. Multicenter randomized clinical trial of supervised exercise therapy with or without feedback versus walking advice for intermittent claudication. *J Vasc Surg.* 2010;52:348–355.

<sup>2</sup> Jones WS, Schmit KM, Vemulapalli S, et al. Treatment Strategies for Patients With Peripheral Artery Disease. Comparative Effectiveness Review No. 118. Agency for Healthcare Research and Quality (AHRQ), Rockville, MD, May 2013.

<sup>3</sup> Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease. *Journal of the American College of Cardiology* (2016), doi: 10.1016/j.jacc.2016.11.007

## Supervision

The proposed NCD explicitly requires “direct supervision of a physician.” **We recommend CMS modify the NCD to allow physicians or non-physician practitioners to meet the direct supervision requirement.** In cardiac rehabilitation, which has similarities to SET, the direct physician supervision requirement creates obstacles to care for some programs, especially in rural areas. It is not always possible or necessary to have a physician immediately available. To remedy this statutory limitation, legislation has been introduced again this year—H.R. 1155—that would allow physician assistants, nurse practitioners, and clinical nurse specialists to supervise cardiac and pulmonary rehabilitation programs. The suggested modification would be consistent with applying the clinically accepted approach for which groups are advocating in the cardiac rehabilitation setting to SET.

## Place of Service

SET can be capably and reliably provided in multiple settings, including the physician office. However, the proposed NCD indicates SET “must be conducted in a hospital or outpatient hospital setting.” **We recommend the final NCD emphasize the outpatient setting rather than any particular hospital setting, saying, “may be conducted in a hospital or outpatient setting, including the physician office.** This approach would also align with cardiac rehabilitation requirements.

## Number of Sessions

Guidelines<sup>4</sup> recommend at least three SET sessions per week. The language used to define coverage states that “a SET program must include...Three sessions per week”, which could be construed to require coverage of exactly three sessions per week. Similar to the language used to define coverage for cardiac rehabilitation, **we suggest CMS indicate SET is covered for “Up to 36 sessions for a 12-week period.”** This change would recognize that the number of sessions needed per week may vary by patient. For example, family commitments, travel obstacles, or work conflicts sometimes prevent patients from completing three sessions in a given week. At the same time, other patients may benefit from completing more than three sessions per week. This change is also consistent with the language in the draft NCD which “proposes that Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time.” This language does not require a specific number of sessions per week.

## Non-Covered Indications

The proposed NCD lists several absolute contraindications to exercise, including amputation. **We request that amputation be removed from the list of non-covered indications.** Patients who have lost a toe or foot, or have had a leg amputation and use a prosthesis, who can ambulate and suffer from claudication, can benefit greatly from SET. Exercise-limiting amputation would be a contraindication, but not all amputation is exercise-limiting.

## Coding

While not under the purview of the NCD process, we urge CMS to consider the impact the NCD will have on practices’ documentation workflows. A CPT code, 93668, does exist to report PAD rehabilitation. This is a status N (noncovered) code that has no physician work and a modest amount of practice expense to account for clinical staff time, supplies, and equipment time. **We encourage the Coverage and Analysis Group to coordinate with the Hospital and Ambulatory Payment Group so**

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<sup>4</sup> Gerhard-Herman MD, et al.

**the latter team may propose accompanying changes during the CY 2018 physician fee schedule rulemaking process.**

Thank you for your time and consideration of these comments. We view this as a significant opportunity to improve patients' care and quality of life and look forward to a final NCD that includes these suggested changes.

Sincerely,

American College of Cardiology  
American College of Radiology  
American Heart Association  
Society for Cardiovascular Angiography and Interventions  
Society for Vascular Medicine  
Society for Vascular Surgery  
Society of Interventional Radiology  
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