



April 1, 2017

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

**Re: Proposed Decision Memo for Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (CAG-00449N)**

Dear Director Syrek Jensen,

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), we are pleased to submit the following comments in response to CMS proposed memorandum for Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD). The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at [www.woundcarestakeholders.org](http://www.woundcarestakeholders.org).

The Alliance is supportive of PAD patients receiving supervised exercise therapy (SET). Providing coverage for SET will increase access to a treatment option in which a significant portion of Medicare beneficiaries will benefit. Evidence shows that SET improves a patients’ quality of life and clinical outcomes. As such, we are pleased that CMS has proposed to provide Medicare coverage of SET for PAD patients. Generally, the Alliance believes that this proposed decision memorandum is well written. However, we do have a couple of specific concerns related to some of the language contained in this proposal. Specifically,

- We do not agree with the CMS proposal regarding the limitation that a SET program must be conducted in a hospital or outpatient hospital setting. The Alliance believes that the setting should not be restricted to hospitals or outpatient hospital settings, and that more patients will benefit from PAD if the number of settings where SET can be delivered is expanded.
- We do not agree with the direct supervision of a physician requirement. The Alliance believes that physicians or non physician practitioners can fill this role.

- We do not agree with the proposed limitations for the SET program. While Medicare Administrative Contractors (MACs) would have discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time CMS has included three sessions per week, with up to 12 weeks of sessions in the policy. While some patients may require only 36 sessions over 12 weeks of sessions or less, other patients may require significantly more sessions across a longer time period to properly treat PAD. Studies have shown continued improvements over a 24 week period for patients participating in a SET. We do not believe that CMS has provided the evidence to support its proposed limitation. The Alliance would like to recommend that the number of visits should be based upon the treatment plan created for an individual patient and not set arbitrarily – which CMS appears to have done in this memorandum.

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Marcia Nusgart R.Ph." in a cursive script.

Marcia Nusgart R.Ph.  
Executive Director

