

Comments to Center for Medicare and Medicaid Services
Medicare Evidence Development & Coverage Advisory Committee Meeting
on Diagnosis and Treatment of Secondary Lymphedema
November 19, 2009

**SVM OFFICERS
2009-2011**

President

Thom W. Rooke, MD
Mayo Clinic
Rochester, Minnesota

President-Elect

Joshua Beckman, MD
Brigham & Women's Hospital
Boston, Massachusetts

Immediate Past President

J. Michael Bacharach, MD,
MPH
North Central Heart Institute
Sioux Falls, South Dakota

Secretary

Susan M. Begelman, MD
Genentech
San Francisco, California

Treasurer

James B. Froehlich, MD, MPH
University of Michigan
Medical School
Ann Arbor, Michigan

TRUSTEES

Jerry Bartholomew, MD
Cleveland Clinic Foundation
Cleveland, Ohio

Robert T. Eberhardt, MD
Boston University School of
Medicine
Boston, Massachusetts

Cindy Felty, MSN, RN, CNP
Mayo Clinic
Rochester, Minnesota

Heather L. Gornik, MD
The Cleveland Clinic
Cleveland, Ohio

Scott Kinlay, MD
Brigham & Women's Hospital
Boston, Massachusetts

Suman W. Rathbun, MD
University of Oklahoma
Science Center
Oklahoma City, Oklahoma

David P. Slovut, MD, PhD
North Shore Medical Center
Swampscott, Massachusetts

Ex-Officio Member

Mark A. Creager, MD
Brigham & Women's Hospital
Boston, Massachusetts

The Society for Vascular Medicine is a professional organization founded in 1989 to improve the integration of vascular biological advances into medical practice and to maintain high standards of clinical vascular medicine.

The Society appreciates the opportunity to provide comments to the Medicare Evidence Development & Coverage Advisory Committee (MedCAC) on the topic of diagnosis and treatment of lymphedema. Our comments will address MedCAC questions 5 and 6, specifically with regard to the questions posed concerning evidence and clinical outcomes related to pneumatic compression devices.

Overview

As practitioners of vascular medicine, we are at the frontline of diagnosis and treatment of primary and secondary lymphedema. Complex decongestive therapy and compression therapy is used as first line of treatment. One of the home treatment modalities we rely upon is use of pneumatic compression devices which we have found through our experience has given appropriate patients clinically meaningful improved health outcomes. Like other successful modalities that have been used for years, pneumatic compression pumps have significant role in treating lymphedema but have not had robust level 1 evidence development. With that understanding, clinicians must base treatment, on the combination of existing evidence, underlying physiology, expert opinion and practice experience to develop practice standards and deliver the best level of care.

Pneumatic compression devices have been part of the lymphedema treatment armamentarium for well over 20 years. We use pump therapy as an adjunct to the home care program for patients, including those of Medicare age, who are unable to manage their condition with compression bandaging and garments and self-massage. Certainly the evidence exists that they produce clinically meaningful outcomes, and we have seen those outcomes ourselves. Many pneumatic compression device studies have demonstrated positive limb reductions.^{i,ii,iii,iv,v,vi,vii} This is a significant outcome because any type of edema is detrimental as it adversely affects the skin's mechanical properties, increasing its susceptibility to injury. Reduction of *lymphatic* edema is even more significant when considering the unique tissue biology of the disorder and associated proliferation of fibrous tissue and, more or less pronounced, proliferation of adipose tissue. Achieving and maintaining tissue reduction is a desirable outcome in that it diminishes tissue proliferation as well as the associated pain, loss of mobility, risk of infection, and psychosocial impact.

We are confident the evidence is sufficient to demonstrate the clinical utility of pumps in lymphedema treatment, especially in light of lymphedema evidence overall, and a growing body of clinical experience and emerging evidence on advanced pump technology buys that confidence. Use of pump technology for lymphedema treatment has until recently been limited to some degree by the fact that the available devices lacked adjustability in terms of pressure application and treatment sequencing, and they offered appliances to treat only the limb. These limitations resulted in some clinician hesitation to recommend them for unsupervised home lymphedema treatment due to the complications that have been associated with them including initiation or exacerbation of genital, chest, abdominal or trunk swelling and induction of a fibrous band at the proximal limb. It is important to note that the parameters for pump treatment considered optimal for lymphedema therapy deviate from those used to treat other forms of edema.

The complications associated with limb-isolating pumps only underscores the need for truncal treatment, a facet of lymphedema therapy whose physiological foundation is well-described in the

literature and that is required regardless of the presence of clinically evident truncal involvement. In current practice, prescription of a limb-only pump for a lymphedema patient must be accompanied with instruction to the patient that the adjacent trunk/chest areas be massaged to clear those areas. Realistically, even the most well-intentioned patient struggles with daily application of effective truncal self-massage. Too often these patients are dealing with an already exhausting daily regimen of dealing with comorbidities as well as restricted mobility, pain issues and exhaustion. Even relatively healthy patients experience inability to reach all areas requiring truncal massage. The end result is often lack of compliance leading to poor outcomes or repeated cycling through professional therapy, problems illustrative of the challenges associated with existing home treatment options available to treat patients whose condition is difficult to control.

In relatively recent years, enhanced understanding of the lymphatic biology has resulted in development of an informed lymphedema treatment paradigm that relies on light pressure applications in specified sequences including treatment to the limb and trunk. Pneumatic compression technology has advanced to emulate that paradigm^{viii} and certain advanced pumps offer the programmability to apply appropriate pressure profiles and sequencing to the limb and trunk. This advancement in pump technology is a welcome adjunct to lymphedema therapy as the home treatment options for the lymphedema patient are few. While preliminary investigation of advanced pump technology has shown significant results,^{ix,x} high level evidence development has not kept pace with this treatment paradigm, yet the widespread clinical acceptance and success of advanced devices testifies to the important role they now play in the home treatment program of some lymphedema patients. Currently a number of research projects are underway to provide evidentiary support and help guide treatment protocols and patient election criteria for advanced devices. We are confident that the positive outcomes we are seeing in clinical practice will be borne out as the data emerges.

Answers to MedCAC Questions

5. Based on our discussion above, we have at least intermediate confidence that there is sufficient evidence that pneumatic compression devices produce clinically meaningful improved health outcomes for patients with secondary lymphedema.

6. We have (intermediate, high) confidence that pneumatic compression devices produce clinically meaningful improved health outcomes for patients with secondary lymphedema. This is based on our discussion of the evidence and our members' years of experience with pumps in clinical practice.

Recommendations

As Medicare undertakes its review of lymphedema treatment, we request that it take into consideration the foregoing information and note that existing scientific published evidence may not wholly inform or reflect the current practice standards used in recommending pumps for lymphedema patients, yet pumps are an important component of the armamentarium. After languishing relative to many conditions, the understanding of lymphatics and lymphedema is emerging at a rapid pace. We strongly recommend that the MedCAC panel, and Medicare, protect lymphedema patient care by maintaining the coverage benefit for advanced pumps.

We will be pleased to discuss with CMS the results of the pending controlled trials when they are available and in the meantime to work with them to develop interim patient selection guidelines for advanced devices while research is pending. Patients dealing with recalcitrant lymphedema must have access to this level of home treatment to avoid costly and devastating complications and/or repeated cycling through professional therapy.

Thank you for your consideration of our comments.

Sincerely,



Thom W. Rooke, MD
SVM President

ⁱ Szuba A, Achalu R, Rockson SG. Decongestive lymphatic therapy for patients with breast carcinoma-associated lymphedema. A randomized, prospective study of a role for adjunctive intermittent pneumatic compression. *Cancer* 2002;95(11):2260-7.

ⁱⁱ Miranda F, Jr., Perez MC, Castiglioni ML, et al. Effect of sequential intermittent pneumatic compression on both leg lymphedema volume and on lymph transport as semi-quantitatively evaluated by lymphoscintigraphy. *Lymphology* 2001;34(3):135-41.

-
- iii Pappas CJ, O'Donnell TF, Jr. Long-term results of compression treatment for lymphedema. *J Vasc Surg* 1992;16(4):555-62; discussion 562-4.
- iv Kim-Sing C, Basco VE. Postmastectomy lymphedema treated with the Wright linear pump. *Can J Surg* 1987;30(5):368-70.
- v Richmand DM, O'Donnell TF, Jr., Zelikovski A. Sequential pneumatic compression for lymphedema. A controlled trial. *Arch Surg* 1985;120(10):1116-9.
- vi Zelikovski A, Haddad M, Reiss R. The "Lympha-Press" intermittent sequential pneumatic device for the treatment of lymphoedema: five years of clinical experience. *J Cardiovasc Surg (Torino)*. 1986; 27(3): 288-90.
- vii Wilburn O, Wilburn P, Rockson SG. A pilot, prospective evaluation of a novel alternative for maintenance therapy of breast cancer-associated lymphedema [ISRCTN76522412]. *BMC Cancer* 2006;6:84.
- viii Mayrovitz HN. The standard of care for lymphedema: current concepts and physiological considerations. *Lymphat Res Biol*. 2009; 7(2): 101-8.
- ix Wilburn, op cit.
- x Ridner SH, McMahon E, Dietrich MSH. Home-based lymphedema treatment in patients with cancer-related lymphedema or noncancer-related lymphedema. *Oncol Nurs Forum*, 2008;35:671-680.