ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

November 5, 2015

Re: Future LCD (L33829) for Pneumatic Compression Devices

Dear Drs. Hoover, Brennan, Mamuya, Moynihan and Whitten;

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am writing to bring to your attention the Alliance's concerns with the future local coverage determination ("LCD") on pneumatic compression devices ("PCDs") published on October 15, 2015 (L33829). This future LCD goes into effect on December 1, 2015. Due to our continued concerns with legal, procedural and clinical issues, the Alliance respectfully requests that you withdraw the future LCD. While we did bring this to Dr. Whitten's attention at the recent DAC meeting at Medtrade, the Alliance wanted to ensure that all the DMEMACs were informed through this letter of our concerns.

We do not believe that there is a need for the future LCD, given the clinically appropriate coverage guidance that is already provided in the existing national coverage determination ("NCD") for PCDs. Indeed, we will be meeting with CMS to discuss the restrictive nature of the future LCD compared with the existing NCD and current LCDs for PCDs that appropriately mirror the NCD. Alternatively, we request that you postpone the implementation date of the LCD so that we, as physician specialty societies and clinical associations with expertise in this area of medicine, have the opportunity to engage in a fruitful discussion and collaboration with you to either craft an alternative LCD based on thoughtful review of current clinical literature and practice standards or eliminate the LCD and simply to continue to use the governing NCD.

We have highlighted below our concerns that the future LCD is both procedurally and clinically flawed. We would appreciate the opportunity to discuss our concerns with you via conference call in the next two weeks.

Background:

The Alliance is a nonprofit multidisciplinary trade association of physician and clinician professional organizations whose mission is to promote quality care and access to products and services through effective advocacy and educational outreach in the regulatory, legislative and public arenas. Many of the Alliance physician specialty societies and clinical associations who treat patients with lymphedema such as the American Venous Forum, Society for Vascular Medicine, American Podiatric Medical Association, American College of Foot and Ankle Surgeons, American College of Phlebology, American Physical Therapy Association, Association for the Advancement in Wound Care, and American Association of Nurse Practitioners have all expressed their concerns regarding the problems with this LCD.

Last year, the Alliance brought to your attention our concerns with the future LCDs issued by all four DME MACs on PCDs. Specifically, the Alliance highlighted two significant issues: (1) the LCDs were released without the required comment period, and (2) the LCDs were fatally flawed in both procedural and clinical areas. Although the implementation of those future LCDs was "delayed" on October 16, 2014, we are

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disappointed and gravely concerned that a new future LCD with virtually the same procedural and clinical flaws has been issued again, one year later.

In reviewing the latest LCD iteration, the Alliance appreciates that you incorporated some of our recommendations. For example, there were issues that clearly had to be addressed, such as including podiatrists as an eligible provider type to order PCDs, rather than have ordering providers limited to physicians (MD, DO) and physician extenders (NP, PA & CNS), due to state scope of practice requirements. We also appreciate that you included chronic venous insufficiency ("CVI") as a cause of secondary lymphedema. However, we are still troubled that the public has not been given an opportunity to comment on the policies included in the future LCD. Further, the latest LCD iteration is plainly more restrictive than the corresponding NCD for PCDs, and it includes clinical requirements that are not based on published evidence, sound science, or current medical practice.

The regulations are clear that the LCD can never be more restrictive than the NCD. We acknowledge that in situations where products or services are overutilized, the LCD may provide clarification (not restriction) of the NCD on appropriate utilization. We submit that in the case of PCDs, there is no evidence of overutilization. Utilization of PCDs in both lymphedema and CVI are already clearly restricted by criteria set forth in the NCD which would indicate that there is a policy in place preventing overutilization. Furthermore, the actual data, taken directly from cms.gov, clearly demonstrates low utilization: in 2014, Medicare expenditures for all three PCDs and the extremity garments used were:

DESCRIPTION	HCPCS	MODIFIER	ALLOWED SERVICES	ALLOWED CHARGES	PAYMENT
DURABLE MEDICAL EQUIPMENT	E0650	**TOTAL**	**784**	**$245,169.13**	**$189,893.61**
DURABLE MEDICAL EQUIPMENT	E0651	**TOTAL**	**19,829**	**$17,384,622.52**	**$13,574,144.12**
DURABLE MEDICAL EQUIPMENT	E0652	**TOTAL**	**353**	**$1,889,437.55**	**$1,479,927.88**
DURABLE MEDICAL EQUIPMENT	E0667	**TOTAL**	**30,468**	**$10,497,871.31**	**$8,225,572.92**
DURABLE MEDICAL EQUIPMENT	E0668	**TOTAL**	**1,952**	**$855,985.49**	**$670,151.28**
DURABLE MEDICAL EQUIPMENT	E0671	**TOTAL**	**460**	**$192,393.39**	**$150,835.84**
DURABLE MEDICAL EQUIPMENT	E0672	**TOTAL**	**22**	**$5,220.74**	**$4,093.01**
		TOTAL	**53,868**	**$31,070,700.13**	**$24,294,618.66**

We submit that out of 54 million Medicare beneficiaries and a $597 billion Medicare budget, this is extremely low utilization, especially considering the millions of Medicare patients suffering from lymphedema and nonhealing venous ulcers.

Thus, the Alliance believes that the significant legal, procedural, and clinical issues are sufficiently substantial to withdraw or postpone the implementation of these LCDs at least until the specific legal and procedural concerns that we have highlighted are addressed on the merits, and until the public has had the opportunity to provide comment as required by the Medicare Program Integrity Manual.

Substantive Flaws that Must be Addressed:

The following examples are illustrative of the additional criteria set forth in the future LCD that significantly alter the existing terms of coverage for PCDs, which diminish or even eliminate access to PCDs to Medicare beneficiaries.

1. **The new LCD criteria for coverage of PCDs are improperly and substantively more restrictive than the corresponding NCD.** In the "Response to Comments to Accompany LCD for Pneumatic Compression Devices" published on October 15, 2015, in response to assertions by stakeholders that the future LCDs issued in 2014 were more restrictive than the NCD, you responded that "[t]he revised LCD broadens the allowed indications and thereby specifically addresses any concern in this area. There is no conflict with the revised LCD and the NCD."

   The Alliance unequivocally disagrees with this response and asserts that the new LCD is clearly more restrictive than the NCD, in violation of Chapter 13, Section 13.5 of the Medicare Program Integrity Manual.

   - The NCD allows for coverage of PCDs for the diagnosis of lymphedema.
     - The new LCD restricts coverage to **severe** lymphedema presenting with **extreme clinical manifestations** (e.g., marked hyperkeratosis with hyperplasia and hyperpigmentation; papillomatosis cutis lymphostatica; deformity of elephantiasis; skin breakdown with persisting lymphorrhea; detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology).
   - The NCD allows for coverage of PCDs after a 4-week trial of conservative therapy when the treating physician determines that the patient has had "no significant improvement or significant symptoms still remain."
     - The new LCD restricts coverage, stating that at the end of the 4-week trial, "if there has been improvement then reimbursement for a PCD is not justified" **even if the improvement is not "significant" or if significant symptoms still remain.**
     - Further, the new LCD extends the 4-week trial timeline to an indefinite trial length, again beyond the bounds of the NCD.
   - The NCD allows for coverage of PCDs coded E0652 for diagnoses of lymphedema and chronic venous insufficiency when the patient presents with unique characteristics that prevent satisfactory treatment with a basic PCD (coded E0650/E0651).
     - The new LCD restricts coverage of E0652 PCDs to only patients who have lymphedema that extends into the trunk/chest/abdomen, thereby excluding E0652 PCD access to patients with lymphedema confined to the limb.
     - The new LCD removes ALL coverage of E0652 PCDs for patients with chronic venous ulcers.

2. **The new LCD criteria remove access to care for populations of patients who currently have access to PCDs, including breast cancer survivors who develop lymphedema as a result of their cancer treatment. This is of particular importance due to the fact that PCDs are the only home lymphedema self-treatment covered by Medicare.**

- In addition to most breast cancer-related lymphedema patients, other populations who will lose access to PCD treatment are:
    - Patients with limb-only lymphedema who have tried and failed all other therapeutic options, including failure of E0650/E0651 PCDs, no longer have access to advanced (E0652) PCDs.
    - Patients with lymphedema resulting in loss of range of motion, fibrosis, pain and disfigurement, but who do not have the extreme presentations listed in the new PCD no longer have access to PCDs to slow the disease progression.

3. **The new LCD was issued without notice to the public of opportunity to comment.** A draft LCD was released for public comment in 2011. The future LCDs released in September 2014 and on October 15, 2015 included significant changes from the draft LCD, yet neither of these future LCDs provided notice of public opportunity to comment as required by the Medicare Program Integrity Manual, Chapter 13, Section 13.7.2. Despite the improper notice and lack of comment period associated with the 2014 release of the future LCD, stakeholder organizations actively furnished information to you and CMS, and protested the flawed policy. Now, a year later, you have published a "Response to Comments" based on the comments you informally received last year. However, that response is insufficient since there was no public notice of an opportunity to comment in 2014, and there is no transparency to be able to understand what comments were taken into account.

4. **The new LCD criteria contain serious clinical flaws.**

    - The new LCD delays access to PCD therapy until the condition is severely disabling and disfiguring. This flies in the face of the goals of lymphedema treatment which are to slow the progression of this chronic and progressive condition to *avoid* that disability and disfigurement. **There is absolutely nothing in the clinical literature that supports delaying treatment while the patient progresses to severe, late stage lymphedema.**
    - The new LCD asserts that there is only one "unique characteristic" identified in the literature that warrants use of an advanced (E0652) PCD rather than the basic PCD. That is inaccurate; clinical literature provides guidance on multiple characteristics that prevent satisfactory treatment with a basic PCD, and further, many of those characteristics are self-evident.[1,2,3,4]
    - The new LCD requires "correction of anemia and hypoproteinemia" as part of conservative therapies required to qualify for the E0652 PCD. This is flawed in two ways: first, these are not "conservative therapies", and second, these are not specifically relevant to appropriate use of PCDs in lymphedema treatment.

The issues outlined above are illustrative, but not all-inclusive, of the identified flaws in the new LCD. Further, it appears that several literature citations provided to you for review last year were either not

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[1] Lee BB, Bergan J, Rockson SG. *Lymphedema: A concise compendium of theory and practice.* 1st ed. Springer 2011.
[2] Rooke, TW. Society of Vascular Medicine: 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. http://vascularmed.org/professional_practice/10-16-09%20MedCAC%20letter.pdf.
[3] Position Statement of the National Lymphedema Network. Topic: *The diagnosis and treatment of lymphedema*. Updated February 2011. www.lymphnet.org.
[4] The diagnosis and treatment of peripheral lymphedema: 2013 Consensus Document of the International Society of Lymphology. *Lymphology*. 2013 Mar;46(1):1-11.

reviewed or disregarded.[5,6,7,8,9,10,11,12,13,14,15,16,17] PCDs are supported by clinical evidence, with new research published as recently as this past month supporting their efficacy and supporting use before reaching a severe, late stage of the condition.[18] We request that you take this clinical evidence into consideration, as required by the Medicare Program Integrity Manual (Chapter 13, Section 13.7.1), in the development of a new LCD.

As we communicated to you last year, our membership – including lymphedema and chronic venous ulcer experts who routinely treat patients with these conditions – stand ready to work with you to craft a policy that provides needed clarity around criteria and also considers the needs of this very deserving population of patients. We would appreciate the opportunity to discuss our concerns with you via conference call in the next two weeks.

[5] Muluk S, et al., Pneumatic compression device treatment of lower extremity lymphedema elicits improved limb volume and patient-reported outcomes. European Journal of Vascular and Endovascular Surgery. 2013 Oct; 46(4): 480-487.
[6] Fife CE, Davey S, Maus EA, Guilliod R, Mayrovitz HN. A randomized controlled trial comparing two types of pneumatic compression for breast cancer-related lymphedema treatment in the home. Support Care Cancer. 2012 Dec;20(12):3279-86.
[7] Adams KE, Rasmussen JC, Darne C, Tan IC, Aldrich MB, Marshall MV, Fife CE, Maus EA, Smith LA, Guilloid R, Hoy, S, Sevick-Muraca EA. Direct evidence of lymphatic function improvement after advanced pneumatic compression device treatment of lymphedema. Biomedical Optics Express 2010 Aug; 1(1); 114-125.
[8] Ridner SH, Murphy B, Deng J, Kidd N, Galford E, Bonner C, Bond SMN, Dietrich MS. A randomized clinical trial comparing advanced pneumatic truncal, chest and arm treatment to arm treatment only in self-care of arm lymphedema. Breast Cancer Res Treat. 2012 Jan;131(1):147-58.
[9] Zaleska Marzanna, Olszewski Waldemar L., and Durlik Marek. Lymphatic Research and Biology. June 2014, 12(2): 103-109.
[10] Chang, CF, Cormier JN. Lymphedema interventions:exercise, surgery and compression devices. *Seminars in Oncology Nursing* 2013,291:1 pp28-40.
[11] Feldman JL, Stout NL, Wanchai A, Stewart BR, Cormier JN, Armer JM. Intermittent pneumatic compression therapy: a systematic review. *Lymphology.* 2012; 45(1):13-25. *"IPC is also a safe and effective intervention for many suffering with chronic lymphedema who have little to no access to medical care in the health care system of proximity. Considering the aging population of the United States, it is wise to recognize interventions that have good clinical utility and are easily and safely applied by patients or their immediate caregivers in an independent, home-structured environment."*
[12] Gurdal SO, Kostanoglu A, Cavdar I, et al. Comparison of intermittent pneumatic compression with manual lymphatic drainage for treatment of breast cancer-related lymphedema. *Lymphat Res Biol*. 2012;10(3):129-135.
[13] Wilburn O, Wilburn P, Rockson SG. A pilot, prospective evaluation of a novel alternative for maintenance therapy of breast cancer-associated lymphedema. *BMC Cancer 2006;* **6**:84.
[14] Huang TW et al. Effects of manual lymphatic drainage on breast cancer-related lymphedema: a systematic review and meta-analysis of randomized controlled trials. *World Journal of Surgical Oncology* 2013, 11:15.
[15] Javid SH, Anderson BO. Mounting evidence against complex decongestive therapty as a first-line treatment for early lymphedema. *Journal of Clinical Oncology* 2013; 31:30 pp. 3737-3738.
[16] Anderson L, et al. Treatment of breast-cancer-related lymphedema with or without manual lymphatic drainage. *ActaOncologica* 2000, 39:3 pp.399-405.
[17] Dayes IS, Whelan TJ, Julian JA. Randomized trial of decongestive lymphatic therapy for the treatment of lymphedema in women with breast cancer. *Journal of Clinical Oncology* 2013; 31:3578.
[18] Karaca-Mandic P, Hirsch AT, Rockson SG, Ridner SH. The cutaneous net clinical and health economic benefits of advanced pneumatic compression devices in patients with lymphedema. *JAMA Dermatol.* Published online October 07, 2015. doi:10.1001/jamadermatol.2015.1895.

We greatly appreciate your attention to this matter and we look forward to working with everyone involved to develop a clinically appropriate LCD.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director