ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

October 13, 2014

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

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I appreciate your speaking to us last week and considering our request to withdraw the new future local coverage determination (LCD) on pneumatic compression devices (PCD) and allowing us to work with you to craft an alternative LCD based on the current clinical literature and clinical practice.

As stated on our call, I am following up with you by sending this letter that addresses further details of the clinical points that the physicians and clinicians raised during our call as well as attaching the literature citations and the articles themselves. The citations for the articles referred to in this letter are on the upper right hand corner of each article. Please note that the attached references are not all-inclusive of potential pertinent literature, and that other stakeholders will likely have additional information to share.

The Alliance is a nonprofit multidisciplinary trade association of health care professional 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. Our clinical specialty societies and organizations 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.

TWO AREAS OF CONCERN IN THE SEPT 2014 DMEMAC PNEUMATIC COMPRESSION DEVICE LCD

On our call, I mentioned that our clinical association members believe that this LCD severely reduces patient access to necessary home treatment for patients who already have few effective treatment options. I noted two separate, but very important, areas of concern with the policy which our members have identified:

1) Procedural/legal issues:

    a. **The final LCD is much more restrictive than the existing National Coverage Decision for PCDs.** Per Medicare regulation, an LCD cannot be more restrictive or conflict with the NCD. Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) created and defined the term "local coverage determination" (LCD) as a decision by a contractor whether to cover a particular service on a contractor-wide basis in accordance with Section 1862 (a)(1)(A) of the Social Security Act (i.e., that the item or service is reasonable and necessary). LCDs may be developed in the absence of an NCD or as a supplement to an NCD as long as the LCD policy does not conflict with national policy. Medicare Administrative

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410 | F 301.530.7946
marcia@woundcarestakeholders.org

Contractors (MACs) must ensure that LCDs are "clear, concise, properly formatted and **not restrict or conflict with NCDs or provisions in interpretive manuals**" (emphasis added).[1]

b. **The final LCD is significantly different than the existing LCD as well as the draft LCD that was released in 2011; yet, this LCD was released as a final policy three years after the draft release with no additional public "comment period."** Medicare regulations require that if the revisions in a new LCD restrict provisions in the existing LCD, a comment period is required. As explained below, several provisions of the final LCD were not included in the draft and significantly restrict coverage to PCDs without a basis in PCD evidence. A public comment period on these provisions is necessary to allow stakeholders to demonstrate these issues and collaborate to craft an appropriate coverage policy.

2) Clinical inaccuracies and lack of evidence base:

a. **Medicare regulations state that Medicare contractors should base LCDs on clinical evidence and consultation with professional societies.**
b. **Many of the new requirements have no basis in either published medical literature or professional standards of practice.**
c. **To our knowledge, professional societies were not asked for their input on this new LCD.**

CLINICAL INACCURACIES IN DRAFT LCD

The clinical issues that our members identified on our call in greater detail include the following:

The new LCD supporting references exclude a significant amount of pertinent evidence-based literature including several relevant articles and texts, specifically those published on PCDs in the recent years.

- Section 13.7.2 of the Medicare Program Integrity Manual (Pub. 100-08, Ch. 13) states, *"Contractors shall provide for both a comment period and a notice period in the following situations… Revised LCDs that Restrict Existing LCDs."* The LCD, in its current form, severely restricts patient access to PCD and vastly deviates from the previously covered indications provided in the existing LCD. Therefore, as mandated in the Medicare regulations, the current LCD should be rescinded and reissued with the appropriate notice and comment period.
- Section 13.7.2 of the Medicare Program Integrity Manual (Pub. 100-08, Ch. 13) states *"Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question."* There is a significant amount of evidence that has been published in the past three years, since the promulgation of the LCD in proposed form that should be given adequate consideration

[1] Centers for Medicare and Medicaid Services, Medicare Program Integrity Manual, CMS Pub. 100-08, Chap. 13, Sec. 13.5 (Rev. 443, Dec. 14, 2012); available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf - last checked March 18, 2013 and found under Regulations and Guidance > Manuals > Internet-Only Manuals (IOMs).

before finalization of this current policy. Studies referenced here are not all encompassing but provide examples of relevant literature not included in the LCD.[2,3,4,5,6]

The new LCD requires patient to present with "chronic and severe" lymphedema of 6 months duration before any potential qualification for PCD:

- This is far more restrictive than the NCD or draft LCD, which both require failure of 4 weeks conservative therapy and do not stratify by severity.
- The LCD does not define what Medicare considers to be a presentation of "severe" lymphedema nor does it refer to accepted lymphedema staging stratification.[7] Regardless of underlying cause, lymphedema will, in the majority of cases, progress in stages if untreated or undertreated.[8]
- **We assert that pneumatic compression is medically necessary and clinically effective in any stage of lymphedema and is effective in more moderate stages to prevent the progression of the condition to a severe stage.**
- Waiting for lymphedema to progress to "severe" (Stage III) before implementing use of a PCD has no basis in the literature, does not represent sound clinical practice, likely results in higher overall health care costs, and creates unnecessary patient suffering to achieve Medicare coverage for PCD use. (This requirement would effectively limit PCD use to patients who have elephantiasis.) **The objective of a lymphedema treatment plan, including use of a PCD, is to help slow the progressive nature of the disease to avoid the extreme disability and cost associated with Stage III lymphedema.** When it is clear that conservative therapy is not effective in management of Stage II lymphedema, daily **home** treatment with a PCD is an effective adjunct to the treatment plan.[9,10] Pneumatic pumps are not an endpoint for treatment when other mechanisms for treatment have failed. Instead, PCDs are most clinically effective when used in conjunction with a clinical treatment plan.
- **Further, this LCD virtually eliminates access to the vast majority of beneficiaries who have lymphedema associated with breast cancer treatment.** These patients rarely progress to Stage III (elephantiasis) yet this population experiences significant disability and pain at Stage II, and often lymphatic damage incurred due to lymph node dissection and scarring is not responsive to conservative therapy alone. A PCD provides the home therapy needed to provide consistent and effective therapy to mobilize fluid out

[2] 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.

[3] 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.

[4] 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.

[5] 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.

[6] Zaleska Marzanna, Olszewski Waldemar L., and Durlik Marek. Lymphatic Research and Biology. June 2014, 12(2): 103-109.

[7] International Society of Lymphology referenced in the 2010 AHRQ Technology Assessment on Secondary Lymphedema (https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id66aTA.pdf. p. 13)

[8] Lee BB, Bergan J, Rockson SG, Editors (2011) *Lymphedema: A concise compendium of theory and practice.* 1st ed. (p. 3) New York, NY: Springer.

[9] Chang CJ, Cormier JN. Lymphedema interventions: exercise, surgery, and compression devices. *Seminars in Oncology Nursing* 2013, 29:1 pp.28-40.

[10] 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."*

of the impaired limb. It is clinically inappropriate to exclude this group of patients from Medicare coverage of PCD therapy as effective home therapy is vital to ongoing treatment of chronic lymphedema.[11]

The new LCD indicates that advanced PCDs (E0652) are not covered for treatment of lymphedema of extremities alone, but only covered when lymphedema extends into trunk or chest; the LCD also states a PCD coded as E0652 is covered for the treatment of lymphedema extending onto the chest, trunk and/or abdomen only when the beneficiary also has lymphedema of an extremity:

- Medically, these conditions can and do occur exclusive of one another. Lymphedema occurs in the trunk/chest in the absence of limb involvement and vice versa.
- This extreme and unsupported limitation is not in the NCD, which states that E0652 PCDs are covered when there are "unique characteristics **that prevent them from receiving satisfactory pneumatic compression treatment"** with E0651 (basic) PCDs. The NCD specifically defines PCDs, stating "[p]neumatic compression devices consistent of an inflatable garment for the arm or leg and an electrical pump that fills the garment with compressed air." [Emphasis added.] While lymphedema in the limb may extend into the trunk, that is not the only "unique characteristic" that can prevent satisfactory treatment with the E0651-level device.
- The DME MACs noted in their comments that unique characteristics are "rare and that an "absence of literature" prevents development of criteria to define them. We disagree. There is information in the literature that can guide criteria development. A number of characteristics that have been shown over the past decade to "prevent satisfactory treatment" with use of a basic PCD. **[12]** Also best practice guidance can be garnered by consultation with professional societies. Many patients with lymphedema with a clinical presentation that is confined to the limb-only **do** experience symptoms or "characteristics" unique to use of E0651 PCDs, but not to use of E0652 devices**.** The same is true for trunk-only lymphedema. When lymphedema is not controlled, or worsens, with use of the E0651 PCD, patients should be afforded appropriate access to the E0652 PCD.
- Also, certain E0652 level devices have been designed to provide effective treatment to accommodate the extreme size of some lymphedematous limbs.

The new LCD requires that conservative therapy must include the component of Manual Lymphatic Drainage (MLD):

- This is much more restrictive than the NCD which states conservative therapy consists of compression, exercise and elevation. This criterion alone will eliminate many patients from ever being able to access a PCD, regardless of medical need.
- **Many patients, including but not limited to those in rural areas or with transportation issues or significant disability/comorbidities, simply cannot access MLD therapy. In fact, a 2013 study of 450 Medicare-aged patients with lymphedema secondary to breast cancer demonstrated that only 13% of those diagnosed with lymphedema received Complete Decongestive Therapy (which included MLD). By comparison, the majority of the diagnosed patients relied on other therapies (bandaging, compression garments, PCDs) to manage their condition.**[13] It cannot be assumed that MLD is universally accessible to Medicare beneficiaries to meet this criterion.

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[11] 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.

[12] Lee BB, Bergan J, Rockson SG, Editors (2011) *Lymphedema: A concise compendium of theory and practice.* 1st ed. (p. 259-260) New York, NY: Springer

[13] Sayko O, Pezzin LE, Yen TW, Nattinger AB. Diagnosis and treatment of lymphedema after breast cancer: A population-based study. *PM R*. 2013;5(11):915-923.

- Medicare limits therapy coverage, which may impede the beneficiary's ability to access MLD, especially if therapy services were necessary for other health conditions.
- **Most importantly, however, is the fact that MLD is not proven to be more effective than conservative therapy with appropriate compression alone. PCD treatment has been shown to be more effective than self-MLD.[14] While certain components of Complete Decongestive Therapy have been shown to positively impact patient outcomes, the MLD component alone is a not a proven modality.**[15,16,17,18,19]
- MLD is a short-term treatment modality, not a long-term daily treatment solution. When the patient is discharged from therapy, he/she must have a long-term self-care home-based plan that does not rely on therapist-delivered treatment.
- This LCD advocates repeated cycling through in-clinic therapy as a method of long-term lymphedema care rather than utilizing effective home treatment using a PCD.

The new LCD requires medications as part of conservative therapy:

- This is more restrictive than the NCD which does not list medication as part of conservative therapy.
- **Use of medications in lymphedema is not supported in the clinical literature. Drug therapy has little, if any, role in the treatment of lymphedema, with the one exception being the use of antibiotics to treat soft tissue infections.**[20]

The new LCD states PCDs are not covered if there is any improvement after use of conservative therapy:

- This is more restrictive than the NCD, which allows for coverage of PCDs after use of conservative therapy when there may have been improvement but "significant symptoms still remain."
- This advocates that patients who see any improvement, no matter how minimal, continue to cycle through repeated 4 week sessions of in-clinic therapy to receive MLD. **This is neither cost effective nor is it in keeping with the preferred treatment paradigm of promoting effective self-care in the home.**
- Delaying implementation of therapeutic interventions in this manner does not represent sound clinical practice. Minimal improvement may not be clinically meaningful. Clinical interventions are made when the clinician determines that the patient, while perhaps exhibiting some incremental improvement, is not achieving the level of therapeutic goals that is appropriate in a given timeframe.

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[14] 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

[15] 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.

[16] Ochatek K, Gradalski T. Manual lymph drainage may not be a necessary component in lymphedema treatment. *J of Pain and Symptom Management* 2010, 38:5.

[17] Anderson L, et al. Treatment of breast-cancer-related lymphedema with or without manual lymphatic drainage. *ActaOncologica* 2000, 39:3 pp.399-405.

[18] Dayes IS, Whelan TJ, Julian JA, et al. Randomized trial of decongestive lymphatic therapy for the treatment of lymphedema in women with breast cancer. J Clin Oncol 2013; 31:3758.

[19] 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.

[20] Rajagopalan S, Dean S, Mohler E, Mukherjee D, Editors (2012) Lymphedema. In *Manual of vascular diseases* (p.544). Philadelphia, PA: Lippincott Williams & Wilkins.

- PCDs are intended to be prescribed as an adjunct to conservative therapy when conservative therapy alone cannot adequately control this chronic, progressive life-long disease.
- **This new LCD requirement will immediately result in an inability to progress patients from in-clinic therapy to a home self-care program and lead to higher overall costs to CMS.**

The new LCD inappropriately addresses coverage of PCDs for treatment of peripheral artery disease.

- PAD and HCPCS E0675 coverage are *not* associated with NCD 280.6, which states in the Indications and Limitations of Coverage section: "Pneumatic devices are covered for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers." (PAD is currently associated with NCD 280.1 which is a general NCD that states products will be covered if "reasonable and medically necessary".)
- Since PAD is technically a contraindication for the devices covered under the NCD, this condition and product should not be addressed under this LCD.

The new LCD also precludes doctors of podiatric medicine (DPMs) from prescribing pneumatic compression devices (PCDs) in the treatment of conditions affecting the lower extremities, such as lymphedema and chronic venous insufficiency with venous stasis ulcers. (The APMA will be sending information under separate cover.)

SUMMARY AND RECOMMENDATIONS

Lymphedema patients have few effective home treatment options to control this progressive and chronic condition. Venous ulcers are notorious for being recalcitrant to healing. PCDs have long offered an effective treatment option that can be used daily at home. This new LCD virtually eliminates access to medically necessary equipment for a significant portion of Medicare beneficiaries who currently qualify for coverage of PCDs to treat their lymphedema and venous ulcers. Implementation of an LCD that is procedurally and clinically flawed, and that lacks basis in current literature and clinical practice is an injustice to Medicare beneficiaries.

We therefore respectfully request that implementation of the new LCD be suspended pending the opportunity for all stakeholders to provide clinical evidence and expert input. The Alliance stands ready to work with you to craft an LCD that provides needed clarity around criteria and meets the clinical needs of this deserving Medicare population.

Thank you so much for your time and consideration of these important issues.

Sincerely,

Marcia Nusgart R. Ph.

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Executive Director