ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

November 2, 2015

Patrick Conway, M.D.
Acting Principal Deputy Administrator
Deputy Administration for Innovation and Quality and CMS Chief Medical Officer

Sean Cavanaugh
Deputy Administrator and Director, Center for Medicare

Liz Richter
Deputy Center Director
Centers for Medicare and Medicaid Services
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Baltimore, Maryland 21244

Re: Future LCD (L33829) for Pneumatic Compression Devices Procedurally and Clinically Flawed and More Restrictive than Corresponding NCD

Dear Acting Principal Deputy Administrator Conway, Deputy Administrator Cavanaugh and Deputy Center Director Richter;

The Alliance of Wound Care Stakeholders ("Alliance") is requesting a meeting with you in the next two weeks to discuss our concerns with the future Local Coverage Determination ("LCD") for Pneumatic Compression Devices ("PCDs") which is procedurally and clinically flawed. We are again asking for the LCD to be withdrawn. There is an urgency to schedule this meeting since the LCD was released in a final and future format on October 15th, again without the required comment period and it goes into effect on December 1, 2015.

Last year, the Alliance brought to your attention an issue with the LCDs issued by the 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. A copy of the Alliance's October 14, 2014 letter is attached for your reference. After many stakeholders, including the Alliance, protested the release of the LCD in 2014, the policy implementation was "delayed" on October 16, 2014 by the DME MACs who indicated that "additional clinical information published since the release of the draft policy is being reviewed."

Now, one full year later, the Alliance is disappointed and gravely concerned that once again we must advise you that the DME MACs have issued a new LCD, again without the required minimum 45-day public comment period, and again with significant procedural and clinical flaws more fully described below.

Last week, we discussed our concerns at the Medtrade meeting with one of the DME MAC Medical Directors, Dr. Richard Whitten, who advised us that the future policy will go into effect on December 1,

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2015. He said that the DME MACs would accept comments only through a reconsideration process. This is unacceptable due to the fact that regulatory procedures were not followed as well as the impact that this policy will have on patient care if it is allowed to go into effect.

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. Therefore, we are again addressing this communication to all of you because the issues described herein include clinical, procedural and DME MAC contractor issues that fall within your purview.

In reviewing the latest LCD iteration, the Alliance appreciates that the DME MACs incorporated some of our recommendations. For example, there were issues that they clearly had to address, 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. They also included chronic venous insufficiency ("CVI") as a cause of secondary lymphedema. However, we are still troubled and frustrated that the DME MACs have released a policy that contains many of the same legal and procedural violations that were highlighted in the October 14, 2014 letter, including publishing an LCD that is plainly more restrictive than the corresponding National Coverage Decision ("NCD") for PCDs. Further, it is disheartening that the DME MACs have again issued an LCD with 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 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 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 new 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 DME MACs "Response to Comments to Accompany LCD for Pneumatic Compression Devices" published on October 15, 2015, in response to assertions by stakeholders that the new LCD was more restrictive than the NCD, the DME MACs responded "The 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 the DME MACs 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 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 LCDs were issued without notice to the public of opportunity to comment.** A draft LCD was released for public comment in 2011. The new LCDs released in September 2014 and on October 15, 2015 include significant changes from the draft LCD, yet neither of these new 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 new LCD, stakeholder organizations actively furnished information to the DME MACs and CMS, and protested the flawed policy. Now, a year later, the DME MACs published a "Response to Comments" based on the comments 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 demonstrate that the DME MACs considered all of the comments received and did not pick and choose which comments to respond to.

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 DME MACs assert 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.

The Alliance notes that in our communications with the DME MACs last year on this subject, our membership – including physician societies who routinely treat patients with these conditions – stood ready to work with the DME MAC medical directors to craft a policy that provided needed clarity around criteria and also considered the needs of this very deserving population of patients. Further, several literature citations were provided for review with information that was apparently either not reviewed or disregarded.[5,6,7,8,9,10,11,12,13,14,15,16,17] It is discouraging that the DME MACs, in their development of this

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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.
[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.

latest LCD iteration, did not follow procedure as required by the Medicare Program Integrity Manual (Chapter 13, Section 13.7.1) to consider the strongest evidence available. Further, we asked our clinical associations whether the DME MACs reached out to garner perspective on evidence and practice from these experts and medical societies who actually treat these patients and who have first-hand knowledge of how the existing evidence is informing current practice, as allowed for in the Medicare Program Integrity Manual (Chapter 13, Section 13.7.1). Our understanding is that this did not occur.

Aside from the procedural defects identified above, of perhaps greatest concern is the DME MACs' apparent lack of understanding regarding the impact of this negative policy change on patients living with lymphedema. Candidly, the Alliance is disturbed that the DME MAC Medical Directors seem to have so little awareness of the disability, both physical and psychological, endured by these patients, and the importance of preserving longstanding home treatment for a disease that is lifelong. PCDs are the only home lymphedema treatment covered by Medicare. Yet, despite this fact, the DME MACs appear to have taken an almost cavalier attitude toward lymphedema as a condition – seeming to think it is acceptable to disallow PCD treatment coverage until the lymphedema patient is completely debilitated with severe lymphedema.

Lymphedema patients live with this condition every day for the rest of their lives and there are so few treatments available to alleviate their suffering. Short term treatment like physical therapy is not a feasible ongoing solution for a lifelong condition. Compression garments are not covered by Medicare and provide insufficient management of lymphedema and chronic ulcers for many patients over the course of a lifetime. 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]

The ongoing issues with the DME MACs' repeated release of flawed LCDs for PCDs must be addressed. The Alliance again is reaching out to the DME MAC Medical Directors to request a collaborative discussion with lymphedema and chronic venous ulcer experts to discuss evidence and practice standards. However, we are requesting a meeting with you in the next two weeks to discuss our concerns with the procedural and clinical flaws included in the future LCD. 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.

Marcia Nusgart R.Ph.
Executive Director

c.c. Tamara Syrek-Jensen, CMS Director, Coverage and Analysis

[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.