ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

January 7, 2016

Peter J. Gurk, M.D.
Medical Director
DME MAC, Jurisdiction D
Noridian Healthcare Solutions
900 42nd Street South
Fargo, ND 58103-2146

RE: Local Coverage Determinations for Pneumatic Compression Devices

Dear Dr. Gurk:

The Alliance of Wound Care Stakeholders ("Alliance") received the letter from the DMDs responding to our correspondence to you of November 5, 2015, in which we stated our numerous concerns regarding the Future LCD for Pneumatic Compression Devices (PCDs) that took effect on December 1, 2015. Now that these LCDs have taken effect, we are writing to you to request that the LCDs be revised to conform to the binding National Coverage Determination for PCDs. Under separate cover, we will be sending a proposed redline version of the LCDs with the appropriate revisions.

The Alliance's request to you and to the other DME MAC medical directors has not changed. The Alliance accepted in good faith the assurances made by CMS and DME MACs that the new LCD was being revised to "mirror the NCD". However, we are extremely disappointed and frankly stunned that the purported LCD "revision" merely encompassed changing two words in the 20-page LCD. Although your letter dated December 10, 2015 explained that the DMDs intended to have the LCD "parallel" the requirements in the NCD, the final LCD publication simply does not do so. We will be meeting with CMS staff shortly to discuss this important issue with them; in the meantime, we are writing to address the key points in our proposed revisions to the LCDs.

The Alliance's request that the LCDs be revised immediately is based on events that have already occurred since the LCDs were published in final form on December 17, 2015. Beneficiaries have been denied access to PCDs twice -- from both the flawed initial LCD and now the new final LCD. In the cases involving the flawed LCD, the payers cited specific language from the flawed LCD; even in cases where patients had tried the basic pump and found it ineffective, these plans denied coverage using the LCD criteria that restricts coverage beyond that permissible under the NCD. Since the publication of the final LCDs, patients have been denied access to PCDs based on criteria that simply do not exist in the NCD.

Our first and foremost concern is the scope of coverage under the LCDs that is far more restrictive than the NCD for pneumatic compression devices. The Alliance respectfully submits

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

that the LCDs are more restrictive and impermissibly conflict with the NCD. Alliance members and its counsel are very conversant in the rules for LCD development set forth in Chapter 13 of the Medicare Program Integrity Manual. We again assert that the new LCD does not merely "clarify" existing requirements as stated by the DMDs, but rather adds a number of new substantive binding criteria that are more restrictive than the NCD; the practical effect of these changes eliminates beneficiary access to PCDs that has long been afforded by the NCD. There is no doubt that if a beneficiary had access to a PCD on November 30, 2015 based on existing criteria, but that same patient no longer qualified for PCD coverage on December 1, 2015 based on new LCD criteria, then those new criteria are more restrictive – and that is the case for a large number of beneficiaries.

Further, the Alliance believes that a remedy is required that does not rely on the reconsideration process in Chapter 13 of the Medicare Program Integrity Manual. That process is limited to consideration of new clinical issues. In sharp contrast, the issues at hand are not clinical, but rather are procedural and are based on the points previously explained to you that the new LCDs are more restrictive than the NCD, which is not permissible as a matter of law under the Program Integrity Manual.

We do understand that LCDs are frequently developed to instruct prescribers and suppliers on Medicare requirements. However, since the changes in the final LCDs are substantive changes that now deny Medicare coverage for an entire class of beneficiaries whose PCDs previously were covered, the LCDs cross the line between an interpretation of the NCD and a concrete restriction of the NCD.

This basic change in the scope of Medicare coverage policy for PCDs can be illustrated through multiple examples, all of which have been addressed in our previous correspondence and meetings. The NCD states that PCDs are "covered in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial." It must be noted here that there are several critical distinctions between the NCD and the LCDs:

- The NCD does **not** limit coverage to "severe" lymphedema, which is the case with the LCDs.
- The NCD does **not** require multiple 4 week trials of conservative therapies, which is required under the LCDs.
- The NCD allows for coverage **if significant lymphedema symptoms still remain** after a 4 week trial of conservative therapy, which is not the case with the LCDs.
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The final LCDs restrict coverage of lymphedema to <u>only</u> patients whose condition has reached a "severe" stage. The term "severe lymphedema" is not part of the NCD lymphedema definition and this new LCD criterion clearly restricts (and therefore conflicts with) the NCD. In your letter of December 10, it is explained that "if the lymphedema is not of sufficient chronicity and severity that it has been possible and appropriate to have at a minimum 'detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely

etiology', then it is logical that the lymphedema is insufficiently 'chronic and severe' to evidence medical necessity for pneumatic compression therapy."

We respectfully disagree with this position for the following reasons:

- The NCD does **not** require "detailed measurements over time." The NCD is quite explicit in its coverage criteria, which require physician evaluation of symptoms and measurements after a 4-week trial of conservative therapy. The new LCD improperly imposes new restrictive and burdensome timelines on the trial of conservative therapy.

  The LCD requirement that lymphedema be classified as "severe" has potentially devastating implications to these patients. The DMDs seem to not be aware that the term "severe" lymphedema has a very specific definition. Lymphedema clinicians generally classify lymphedema in stages, with the most serious level being Stage III, or "severe" lymphedema. It is important to note that the stage of lymphedema is not defined exclusively by size but also by tissue consistency. A number of references discuss lymphedema staging; the most common method of staging was defined by the Fifth WHO Expert Committee on Filariasis:

  - **Stage 0 (latent)**: The lymphatic vessels have sustained some damage which is not yet apparent. Transport capacity is still sufficient for the amount of lymph being removed. Lymphedema is not present.
  - **Stage 1 (spontaneously reversible or "mild")**: Tissue is still at the pitting stage: when pressed by the fingertips, the affected area indents, and reverses with elevation. Usually upon waking in the morning, the limb or affected area is normal or almost normal in size.
  - **Stage 2 (spontaneously irreversible or "moderate")**: The tissue now has a spongy consistency and is considered non-pitting: when pressed by the fingertips, the affected area bounces back without indentation. Fibrosis found in stage 2 lymphedema marks the beginning of the hardening of the limbs and increasing size.
  - **Stage 3 (lymphostatic elephantiasis or "severe")**: At this stage, the swelling is irreversible and usually the limb(s) or affected area is very large. The tissue is hard (fibrotic) and unresponsive; some patients consider undergoing reconstructive surgery, called "debulking". This remains controversial, however, since the risks may outweigh the benefits, and the further damage done to the lymphatic system may in fact make the lymphedema worse.

The new LCDs condition Medicare coverage for a PCD on the beneficiary having "severe" lymphedema; this is plainly inconsistent with the NCD, but also prevents access to PCD use when it can help the patient the most – to keep Stage II lymphedema from progressing to "severe" or Stage III lymphedema. Historically, based on the NCD, lymphedema patients have had access to PCDs to treat Stage II lymphedema that was not responding to conservative treatment. This new LCD criterion, by limiting coverage to severe lymphedema (elephantiasis) is not only more restrictive, but also has significant potential to harm patients.

The Alliance is also concerned with the statement in the LCD that "[a]t the end of the four-week trial if there has been improvement, then reimbursement for a PCD is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart." **This statement unambiguously conflicts with the NCD, which requires a single 4-week trial, not repeated trials with ongoing assessments, and allows for coverage if significant symptoms remain at the end of that 4 week period.** This conflict cannot be avoided by relying on the next sentence in the LCDs, which states that "[o]nly when no significant improvement has occurred in the most recent four weeks ... may…coverage for a PCD [be]considered." [Note that the word "significant" is one of the two words that was changed in the final LCD.] However, this statement is incongruent with the preceding two sentences in the LCD. The qualifying term "significant" must be inserted before the word "improvement" in each of the three sentences, and the phrase "if significant symptoms still remain" must be inserted for this criterion to accurately reflect the NCD.

The Alliance's next concern is that the NCD allows for coverage of an E0652 level PCD "when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment" using the E0650 or E0651 level PCD. However, the LCDs have inserted the following new coverage restrictions for E0652 PCDs that are **not** part of the NCD:

- For lymphedema patients, coverage of E0652 PCDs is now restricted to only patients with lymphedema extending into the chest, trunk or abdomen, removing coverage that has long existed for patients with lymphedema confined to the limb.
- For patients with nonhealing venous ulcers, all coverage of E0652 PCDs has been completely eliminated.

This is not an expansion of coverage for E0652 devices as had been represented to the Alliance. Prior to December 1, 2015, patients with limb-only lymphedema had access to E0652 PCDs when criteria were met. After December 1, 2015, patients with limb-only lymphedema can no longer qualify for the E0652 PCD, regardless of whether they meet all other criteria.

For this to have been an expansion of Medicare coverage, the new E0652 coverage of trunk/chest lymphedema would have to be *in addition* to limb-only lymphedema coverage. However, the new LCDs do not provide *additional* coverage. On the contrary, they removed E0652 coverage of limb-only lymphedema (which is certainly not part of the NCD).

Further, the removal of coverage for E0652 for all patients with nonhealing venous ulcers is clearly more restrictive than the NCD.

In addition to these fundamental procedural flaws, we were surprised that none of our recommendations for references were included in the final LCD even though they included new literature. We ask that any LCD reflect the substantive points addressed in these new references.

Based on the points addressed in this letter, we request that the LCDs be revised in accordance with the proposed redline developed by the Alliance, so that the LCDs truly mirror the binding NCD. At your convenience, we are available to meet with you to discuss the revisions to the LCDs.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

cc: Stacy Brennan, M.D.
Robert D. Hoover, Jr., M.D., M.P.H.
Wilfred Mamuya, M.D., Ph.D.