

September 23, 2011

Paul J. Hughes, MD

Medical Director, DME MAC, Jurisdiction A

NHIC Corp.

75 Sgt. William B. Terry Drive

Hingham, MA 02043

Re: Draft Local Coverage Determination for Pneumatic Compression Devices (DL11492)

Dear Doctors Hughes, Brennan, Hoover and Whitten;

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), I am pleased to submit the following comments in response to the Draft Local Coverage Determination for Pneumatic Compression Devices (PCDs). The Alliance is a 501 (c) (6) multidisciplinary trade association consisting of 19 physician, clinical, provider, and patient organizations, whose mission is to promote quality care and patient access to wound care products and services. These comments were written with the advice of Alliance organizations that not only possess expert knowledge in complex acute and chronic wounds and lymphedema, but also in wound care and lymphedema research.   We appreciate the opportunity to offer our comments.

As stated in our presentation at the August 30, 2011 DME MAC meeting, the Alliance supports the addition of coverage of appliances for the treatment of lymphedema that extends into the chest, trunk and/or abdomen. We believe that this represents significant progress in the understanding of lymphedema and the needed for comprehensive, effective treatment. However, we do wish to provide our concerns on these specific

portions of the policy, as the potential ramifications to our patient populations are significant:

* Exclusion of podiatrists and other providers to prescribe PCDs
* Secondary lymphedema coverage limitations
* Coverage for lymphedema secondary to chronic venous insufficiency
* Draft LCD conflicts with the corresponding National Coverage Determination (NCD)for PCDs 280.6
* Coverage criteria for lower extremity peripheral artery disease

**Exclusion of podiatrists and other providers to prescribe PCDs**

The draft LCD states the following: “Podiatrists and other providers are excluded because management of the systemic intravascular changes and fluid shifts that may be caused by the use of a PCD is beyond their scope of practice.”

The Alliance has the following questions and concerns:

* What is the rationale or clinical evidence that the DME MACs used to come to the conclusion that it is beyond the scope of practice of podiatrists and other providers to prescribe PCDs?
* We have concerns regarding the LCD since the scope of practice for podiatrists is determined by the licensing boards in each state. The use of pneumatic compression devices is within the scope of practice of podiatrists. It is the purview of the state licensing boards, not the DME MACs to determine the scope of practice of podiatrists including their ability to prescribe pneumatic compression devices.
* Podiatrists are trained to recognize and diagnose the contraindications for the use of pneumatic compression devices which include congestive heart failure and kidney disease conditions. It is only if these disease states and the pneumatic compression device contraindications were ignored – by any provider or specialist – might possible systemic side effects, such as intravascular changes and fluid shifts occur.

In summary, the Alliance opposes the policy of limiting treatments or prescriptions that are clearly within the scope of podiatric practice based on the possibility that side effects may occur. Podiatrists by their education, training and experience are capable of identifying systemic complications such as intravascular changes and fluid shifts that rarely, but might occur with the use of a pneumatic compression device. If such an emergency occurred, like any treating physician, podiatrists are trained to institute emergency management of the patient, and refer the patient to the appropriate source for care of such complications.

**Recommendations:**

The Alliance recommends that the sentence in question be removed and include the following instead:

“Prescriptions for PCDs used to treat lymphedema or chronic venous insufficiency with ulceration (E0650-E0652) are limited to providers enrolled in Medicare, licensed to utilize PCDs within their scope of practice and authorized by Medicare to prescribe as "physicians".

**Secondary lymphedema coverage limitations**

The draft LCD states that PCDs will be covered for one of the following conditions:

1. The treatment of primary lymphedema
2. The treatment of secondary lymphedema caused by one of more of the following:

surgery, radiation therapy, trauma, lymphatic obstruction by a tumor, lymphatic filariasis, chronic venous insufficiency with venous stasis ulcers.

The Alliance has strong concerns regarding the limitations for coverage of secondary lymphedema since patients with lymphedema secondary either to an etiology not set forth in the draft LCD or to an uncertain cause*,* despite a clear-cut diagnosis of lymphedema, will be denied coverage of a pneumatic compression device. The treatment for lymphedema, whether it is primary or secondary to *any* etiology, is the same.

The Alliance understands that the DME MAC medical directors need to craft a policy that helps ensure appropriate utilization. However, limiting patient access to needed care based on underlying etiology is not the answer. Lymphedema is distinguished from other forms of edema based on the physical exam that reveals lymphedema-specific signs and symptoms (other than swelling) that are well-documented in medical literature.[[1]](#footnote-1)-5 At the August 30, 2011 DME MAC meeting, we stated that the Alliance would speak to its participating organizations and give recommendations of diagnostic criteria that could be used in this policy. The physician experts turned to the literature and their own professional experience in treating patients with lymphedema and came up with these criteria:

* Positive Stemmer’s sign
* “Orange peel” skin changes (also called cobblestoning or peau d’orange)
* Swelling of dorsum of foot (“buffalo hump’)
* Hyperkeratosis
* Presence of papillomas
* Lymph vesicles
* Lymphorrhea (lymph fluid leakage)
* Cutaneous fibrosis

Some excerpts of the literature that address these diagnostic criteria are as follows:

*“The diagnosis of lymphatic vascular disease relies heavily on the physical examination. Lymphedema, even when superimposed upon a more complex vascular presentation, is most often readily identified by its* ***physical characteristics****, including edema,* ***peau d’orange, cutaneous fibrosis, and positive Stemmer’s sign*** *(the inability of the examiner to “tent” the skin at the base of the digits in the involved extremity)….****in all cases, the hallmark of lymphedema is the presence of cutaneous and subcutaneous thickening*** *which uniquely identifies the lymphatic pathogenesis of edema formation.”* Rockson SG. Diagnosis and management of lymphatic vascular disease. J Am College Cardiology. 2008; 52(10):799-806.

*“Evidence for Lymphatic Failure in Venous Disease. The more advanced the venous disease, the more likely that edema is present. At first, it is reversible and markedly affected by gravity. With time, however, the clinical features of lymphedema begin to appear, including the* ***characteristic skin changes*** *of* ***hyperkeratosis*** *and* ***papillomatosis****….* Mortimer PS. Implications of the lymphatic system in CVI-associated edema. Angiology 2000; 51(1):3-7.

*“The diagnosis of lymphedema in the lower extremities starts with the appearance of* ***“Stemmer’s sign”*** *– the inability to pinch a fold of skin at the base of the toes. The* ***dorsum of the foot also can appear squared off.*** *Dermal changes that follow include…****hyperkeratosis, skin creases, fibromas, lymphangiomas and papillomas****.”* Fife CE, Carter MJ. Lymphedema in the morbidly obese patient: Unique challenges in a unique population. Ostomy Wound Manage 2008; 54:44-56.

**Recommendation:** The Alliance strongly recommends that the LCD be revised to allow for coverage of PCDs for any lymphedema patient, regardless of underlying etiology, when the patient’s lymphedema has been confirmed by means of diagnostic criteria established set forth above and when other pertinent criteria outlined in the LCD are met.

**Coverage for lymphedema secondary to chronic venous insufficiency**

Further illustration of the concern expressed above is the draft LCD’s restriction of coverage for lymphedema secondary to CVI to only patients who have venous stasis ulcers. Lymphedema that occurs as a result of chronic venous insufficiency (phlebolymphedema) requires the same treatment as any other type of lymphedema, regardless of whether the patient presents with ulcers. Also, the lymphedema associated with CVI can progress to be very severe; it is not a “mild”condition.

Phlebolymphedema begins as venous insufficiency wherein the increase in venous hypertension results in increase in interstitial fluid. Initially the lymphatic system will drain this excess fluid, however when the excess fluid burden is prolonged, the lymph flow becomes much greater than the lymphatic system’s transport capacity, and chronic lymphedema develops. The morphological characteristics of other types of lymphedema also apply to phleblymphedema including interstitial fibrosis, degenerative changes in the lymph capillaries and lymph collectors, and over time regional lymph nodes are characterized by significant fibrosis.[[2]](#footnote-2)5Clinical features of lymphedema appear including hyperkeratosis and papillomatosis, most notably in the submalleolar and retromalleolar regions. Damaged lymph networks in CVI have been demonstrated by use of fluorescence microlymphography.[[3]](#footnote-3)6

The implications of lymphatic insufficiency associated with venous disease are certainly not ‘mild’ symptoms nor are they limited to ulcers; they include the symptoms seen with any type of lymphedema, including:

* Increased risk of infection, particularly cellulitis, a known consequence of lymphatic insufficiency but not venous disease. Approximately one-third of lymphedema patients experience cellulitis, sometimes recurrently, leading to further lymphatic deterioration thereby establishing a vicious cycle.[[4]](#footnote-4)7
* Skin changes including hyperkeratosis, papillomatosis, fibrosis, and even elephantiasis.[[5]](#footnote-5)8

Phlebolymphedema can be diagnosed based on a detailed history and physical exam, and can be differentiated from other conditions based on the presence of lymphedema- specific symptoms as outlined in the above section.

**Recommendations:** The Alliance strongly urges that lymphedema secondary to CVI, with or without ulcers, be covered in the same manner as lymphedema secondary to any other etiology. Also, the reference of lymphedema secondary to CVI as being “mild” should be eliminated from the draft LCD.

**Draft LCD conflicts with the corresponding National Coverage Determination (NCD)for PCDs 280.6**

The Alliance has concerns that in certain circumstances, the draft LCD conflicts with the NCD 280.6 for PCDs. In section 13.5 of the Medicare Program Integrity Manual, CMS states that an LCD may neither restrict nor conflict with an NCD by stating the following:

*“The LCD shall be clear, concise, properly formatted and not restrict or conflict with NCDs or coverage provisions in interpretive manuals. If an NCD or coverage provision in an interpretive manual states that a given item is ‘covered for diagnoses/conditions A, B and C,’ contractors should not use that as a basis to develop LCD to cover only ‘diagnoses/conditions A, B and C.’ When an NCD or coverage provision in an interpretive manual does not exclude coverage for other diagnoses/conditions, contractors shall allow for individual consideration unless the LCD supports automatic denial for some or all of those other diagnoses/conditions.”*

Three situations where we believe that there is a conflict are:

1. Coverage criteria for secondary lymphedema is more restrictive in the draft LCD than the NCD. The draft LCD lists a number of etiologies as causes for secondary lymphedema and will only cover those. However, the NCD has no such limitation and will specifically permit conditions “with other causes.” The Alliance’s significant concerns and recommendations on this issue have been set forth separately above.
2. Coverage for CVI with ulcers is restrictive as compared with NCD coverage.

This is another situation where the LCD may not decline coverage in circumstances where the corresponding NCS permits it.

In 2001, CMS announced that it would cover the use of PCDs for patients with CVI with significant ulceration of the lower extremities. The provision of NCD 280.6 permitting this coverage reads as follows:

*“Pneumatic compressions devices are covered in the home setting for the treatment of CVI of the lower extremities only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a 6 month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.”*

In contrast and in direct conflict with the NCD, the draft LCD coverage provision for CVI reads as follows:

*“As required by CMS NCD for Pneumatic Compression Devices (280.6), a pneumatic compression device (E0650, E0651) is covered in the home setting for the treatment of secondary lymphedema caused by CVI of the lower extremities only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a six-month trial of conservative therapy.”*

Thus, the draft LCD covers CVI *only* if it is associated with secondary lymphedema and if there has been a six-month trial of conservative therapy. This directly conflicts with the NCD, which permits coverage of CVI with ulcers regardless of whether it is associated with secondary lymphedema.

1. The LCD further restricts the scope of the NCD in that it significantly limits the unique characteristics that warrant use of a PCD with calibrated gradient pressure. The NCD states:

*“The only time that a segmented, calibrated gradient pneumatic compression device (HCPCs code E0652) would be covered is when the individual* ***has unique characteristics[plural] that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device*** *in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber.”[Emphasis added.]*

The NCD does not limit the “unique characteristics” required for coverage. A treating physician may certainly identify unique characteristics other than chest or trunk swelling that prevent a patient from “receiving satisfactory pneumatic compression treatment using a nonsegmented device.” Many of this patients can benefit from the clinical features offered by the more advanced E0652 device.

**Recommendations:**

* Since the draft LCD directly conflicts with the NCD, which allows coverage of CVI with ulcers regardless of a comorbidity of lymphedema, the coverage provision of the NCD should be preserved.
* “Unique characteristics” should not be limited to chest/trunk swelling as that is far more restrictive than the NCD.
* E0652 devices should be covered when the patient has used an E0650/E0651 at home for a minimum of 4 weeks with oversight by a competent technician or therapist and it is ineffective in treating the patient’s condition.
* To ensure an adequate trial of the E0651/E0650, the medical record must contain information documenting outcomes that demonstrate the patient failed to improve with use of the E0650/E0651including a detailed description of therapies used in conjunction with the pump and adjustments made to address issues, and objective clinical details of why E0650/E0651 device and adjunct therapies were not effective.

**Coverage criteria for lower extremity peripheral artery disease (PAD)**

The Alliance has concerns with the coverage policy limitations for E0675- pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system). Specifically we have three areas of concern:

* Restricted prescribing
* The need for no revascularization options to prescribe
* Coverage criteria is very narrow

Restricting coverage solely to vascular surgeons would limit the use of arterial pumps for all others who treat patients with wounds; thus, other providers such as podiatrists, internists and vascular medicine specialists would lose prescribing privileges. Secondly, we have concerns that in the draft LCD the patient has no revascularization options. The patient should not be forced to have surgery and should be allowed to have a non-invasive procedure. Patients who are poor surgical candidates or who prefer not to undergo surgery should have the medical option of an arterial pump for CLI and wound healing.

**Recommendation**

It is our understanding that the DMEMACs have been working with stakeholders to develop a coverage policy that would be more appropriate. We have included such a policy in Appendix A and would recommend that the DME MACs eliminate the current language in the draft LCD regarding coverage for PAD and adopt this. We would also suggest that to avoid confusion, that the DME MACs consider making this a separate LCD from the pneumatic compression devices.

We appreciate your consideration of our comments. We would be pleased to serve as a resource to you while you evaluate the comments in determining the final LCD.

Sincerely,



Marcia Nusgart R.Ph.

Executive Director

**Appendix A**

**Draft LCD for Arterial Insufficiency**

E0675 is covered in a patient meeting all of the following coverage criteria:

1. Patient has one or more of the following presentations n the involved limb(s):
   1. Claudication (Ambulation-induced muscle pain including not focal to a joint area) with onset or worsening of symptoms within 5 minutes or 100 meters (whichever occurs first) of casual walking and resolution of symptoms within 10 minutes of subsequent rest 1,2 ***or***
   2. Critical Limb Ischemia (CLI) presenting with lower extremity ischemic rest pain, tissue loss, , or gangrene, Chronic symptoms of pain at rest continuing to currently require pain medication and documented by objective studies to be on an ischemic basis3 ***or***
   3. Acute limb ischemia presenting with the 6 “Ps” that suggest limb jeopardy: Pain, Paralysis, Parasthesias, Pulseless, Pallor, and Polar 4.
2. Patient has in the involved limb,
   1. An ABI of 0.71 - 0.85 with confirmation of PAD with an alternative diagnostic test detailed below (2d)5.  ***or***
   2. An ABI >1.3 ***and*** toe systolic pressure <50mmHg.***or***
   3. An ABI of ≤ 0.7 or a toe pressure <50mmHG ***or***
   4. Evidence of PAD confirmed by one or more of the following laboratory studies: Segmental pressure exam, Pulse volume recording, Continuous Doppler ultrasound, Duplex ultrasound, Treadmill exercise testing, Magnetic Resonance Angiography, Computed Tomography Angiography, Contrast Angiography (6)
3. a. For patients with moderate PAD (Claudication without CLI or acute limb ischemia) there must be documented evidence that the patient has (contraindications to) or not responded to a 6 month trial of optimal pharmacologic therapy ***or***

b. For patients with severe PAD (Rutherford Category 4, 5 or 6), CLI (resting pain, ischemic ulceration, gangrene), acute limb ischemia, or impending amputation, documented evidence of pharmacologic therapy and exercise regimen may be waived7,8 ***or***

c Individuals with PAD where an appropriate, documented, regular exercise program has not achieved adequate symptomatic improvement. or those who have significant functional impairment (e.g., angina, heart failure, chronic respiratory disease, or orthopedic limitations, or those who fall under the 4th point.) who are unable to regularly exercise.9

4) Individuals with lower extremity PAD who continue to smoke or use other forms of tobacco must be actively participating in a comprehensive smoking cessation intervention including behavior modification therapy, nicotine replacement therapy, or bupropion.10

1. Individual with lower extremity PAD who is not a suitable candidate for either endoscopic (artherectomy) or open surgical revascularization. 11
   1. Individual who has history of a prior vascular surgery without symptomatic improvement or,
   2. Individual with lower extremity PAD who has documented small vessel disease (calcification) where a surgical procedure is not likely to improve peripheral circulation or associated symptoms. .
   3. “Bridge” treatment while awaiting surgery is not grounds for coverage
   4. A patient’s declining recommended surgery is not grounds for coverage.
2. All usual DMEPOS requirements must be met (valid physician’s order).

Continued Rental Criteria

If approved, E0675 will be allowed on an initial rental basis for four months.12 Serial review by the physician must document:

* 1. Documentation of clinical improvement substantiating the physician’s decision to continue prescribing the therapy. Examples of clear and convincing documentation include one or more of the following:
* Ischemic/claudication pain relief with serial visual analog scale (VAS) pain evaluation,
* Improvement in quality of life as measured by SF-36 functional assessment scale or another clinically validated instrument.13,14
* Significant wound improvement (>50% surface area healed or complete healing,
* Significant (>0.1) improvement in the ABI.

Note: if the documentation is not clear and convincing after four months of use, continued use beyond this point is not medically necessary.

**Comments & References**

* + 1. This is the most common presenting symptom of lower extremity PAD. Claudication does not indicate severity of disease, long term limitation, or potential limb loss (JAMA 2006 Jul 5; 296(1):41-42).
    2. The location of pain or discomfort is buttocks thigh or calf muscles. The characteristics of discomfort are cramping, aching, fatigue, weakness or frank pain (ACC/AHA Guidelines for the management of PAD 2006., J Vasc Surg, 31, Dormandy JA, Rutherford RB, for the TransAtlantic Inter-Society Consensus (TASC) Working Group, Management of peripheral arterial disease (PAD), S1–S296,
    3. Patients with CLI usually present with limb pain at rest, with or without trophic skin changes or tissue loss. The discomfort is often worse when the patient is supine (e.g., in bed) and may lessen when the limb is maintained in the dependent position. Typically, narcotic medications are required for analgesia (Journal of the American College of Cardiology © 2006 by the American College of Cardiology Foundation and the American Heart Association, Inc. Published by Elsevier Inc.)
    4. Acute limb ischemia arises when a rapid or sudden decrease in limb perfusion threatens tissue viability. This form of CLI may be the first manifestation of arterial disease in a previously asymptomatic patient or may occur as an acute event that causes symptomatic deterioration in a patient with antecedent lower extremity PAD and intermittent claudication. Although attempts have been made to define various levels of ischemia (Rev Cardiovasc Med 2002;3 Suppl 2:S2– 6), it is frequently not possible to precisely delineate the status of the patient with an acutely ischemic limb, because many of the classification schemes are based on subjective clinical criteria and not discrete end points. The hallmark clinical symptoms and physical examination signs of acute limb ischemia include the 5 “Ps” that suggest limb jeopardy: pain, paralysis, paresthesias, pulseless, and pallor. Some clinicians would also include a sixth “P,” polar, to indicate a cold extremity. (ACC/AHA Guidelines for the management of PAD 2006 pp10-11

5. For individuals who present with classic claudication and in whom the ABI is borderline or normal (0.91 to 1.30) or supranormal (greater than 1.30), alternative diagnostic strategies should be used (including the toe-brachial index, segmental pressure examination, or duplex ultrasound to confirm the lower extremity PAD diagnosis (ACC/AHA Guidelines for the management of PAD 2006 p 7).

6 A 6-minute walk test may be reasonable to provide an objective assessment of the functional limitation of claudication and response to therapy in elderly individuals or others not amenable to treadmill testing. (ACC/AHA Guidelines for the management of PAD 2006 p 15

Rutherford's Categories for the Classification of PAD

|  |  |
| --- | --- |
| Category | Clinical |
| 0 | Asymptomatic |
| 1 | Mild Claudication |
| 2 | Moderate claudication |
| 3 | Severe claudication |
| 4 | Ischemic rest pain |
| 5 | Minor tissue loss |
| 6 | Ulceration or gangrene |

From: J Vasc Surg 2000; 31: S1-S296

In such patients where amputation is the only option for symptomatic relief, HPIPC is the last resort to limb salvage. Also the level of ischemic pain is such that any form of exercise is not tolerated. Ref. Sultan, Esan, Fahy Vascular 2008; 16(3):130-139. And Kostantinos, Nicolaides: Annals of Surgery 2005; 241:431-441

1. Patients with intermittent claudication should have significant functional impairment with a reasonable likelihood of symptomatic improvement and absence of other disease that would comparably limit exercise even if the claudication was improved (e.g., angina, heart failure, chronic respiratory disease, or orthopedic limitations) before undergoing an evaluation for revascularization. *(Level of Evidence: C (* ACC/AHA Guidelines for the management of PAD 2006 p 7)
2. Physician advice coupled with frequent follow-up achieves 1-year smoking cessation rates of approximately 5% compared with only 0.1% in those attempting to quit smoking without a physician’s intervention help people stop smoking. (Arch Intern Med 1995;155:1933–41.42). Pharmacological interventions such as nicotine replacement therapy and bupropion achieve 1-year smoking cessation rates of approximately 16% and 30%, respectively (N Engl J Med 1999;340:685–91.).

Our findings demonstrate that symptom relief is measurable in 83% of the subjects at 16 weeks, 42% at 12 weeks and 11% at 8 weeks. Interim analysis of our HPIPC RCT presented at the Annual Symposium on Advanced Wound Care Dallas TX April 2009. In the Kakkos study, symptomatic relief was best (p<0.05 compared to supervised exercise) after 6 months of HPIPC therapy . Ref. Kakkos, Geroulakos, Nicolaides Eur J Vasc Surg 2005; 30, 164-175.

Ref. Kostantinos, Nicolaides: Annals of Surgery 2005; 241:431-441

Ramaswami, D’Ayala, Hollier et al., J Vasc Surg 2005; 41 (5): 794-800.

Delis, Nicolaides, Wolfe, et al.,J Vasc Surg 2003; 13: 650-651

1. Lee BB, Andrade M, Bergan J, Boccardo F, Campisi C, Damstra R, Flour M, Gloviczki P, Laredo J, Piller N, Michelini S, Mortimer P, Villavicencio JL. Diagnosis and treatment of primary lymphedema. Consensus Document of the International Union of Phlebology (IUP)-2009. *International Angiology* 2010;29(5) 454**-**470.

   2Mortimer PS., Implications of the lymphatic system in CVI-associated edema. *Angiology* 2000;51(1)3-7.

   3Rockson SG., Diagnosis and management of lymphatic vascular disease. *J Am Coll Cardiol*.2008; 52(10):799-806.

   4Cohen SR, Payne DK, Tunkel RS. Lymphedema: Strategies for Management. *Cancer* 2001 Aug 15:92(4Suppl):980-987.

   5Fife CE, Carter MJ. Lymphedema in the morbidly obese patient: Unique challenges in a unique population. Ostomy Wound Manage 2008; 54:44-56. [↑](#footnote-ref-1)
2. 6 Foldi M, Foldi E, Kubik S, eds. *Textbook of Lymphology for Physicians and Lymphedema Therapists*. 5th Ed, Urban & Fischer, Munich 2003:p. 360. [↑](#footnote-ref-2)
3. 7 Bollinger A, Isenring G. Franzeck U. Lymphatic microangiopathy: a complication of severe chronic venous insufficiency. *Lymphology* 1982;15:60-65. [↑](#footnote-ref-3)
4. 8 Mortimer PS. Implications of the lymphatic system in CVI-associated edema. *Angiology* 2000;51(1) p.6-7 [↑](#footnote-ref-4)
5. 9 Ibid. [↑](#footnote-ref-5)