WOUND CARE STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

July 18, 2013

Garrett Foulke, MD, MMM
Editor-in-Chief
MCG
901 Fifth Avenue, Suite 2000
Seattle, WA 98164

RE: Intermittent Pneumatic Compression (IPC) Guidelines (ACG: A-0340 AC)

Dear Dr. Foulke,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am writing to express our concerns regarding the Milliman Care Guidelines for IPC (17th Edition). Milliman's position that intermittent pneumatic compression (IPC) is inappropriate for the treatment of lymphedema and chronic venous ulcers is simply inaccurate. The impact of these guidelines is significant as third-party payers adopt them as basis for denial of coverage for these devices, effectively removing access to a valuable therapy option for patients who have so few treatment options to begin with. The importance of accuracy is paramount.

The Alliance of Wound Care Stakeholders is a multidisciplinary trade association representing 16 physician and clinical organizations whose mission is to promote quality care and patient access to products and services. These comments were written with the advice of Alliance organizations that not only possess expert knowledge of chronic wounds and lymphedema, but also are leaders in wound care and lymphedema research. The members of these clinical specialty societies such as the Society of Vascular Medicine and American Venous Forum are vascular surgeons, podiatrists and vascular medicine specialists who treat patients with wounds and lymphedema. A list of our members can be found on www.woundcarestakeholders.org.

Our comments include both general and specific concerns. In general, the guideline appears to confuse different types of IPC pumps with different modes of action and different intended uses. This guideline appears to have been written to address IPC pumps used intraoperatively and postoperatively in a hospital setting for prophylaxis of deep vein thrombosis (DVT). However, the data used to formulate guidelines for DVT prophylaxis is not applicable to IPC pumps that are commonly used for home treatment of lymphedema and chronic venous insufficiency with nonhealing ulcers (CVI/CVU). These intended uses are vastly different in application, indications for use, and the patient population. Currently, the MCG position is inappropriate regarding IPC pumps for the use in lymphedema and CVI/CVU, since it is based on the limited medical studies cited in the Milliman review. If the authors intended to review the evidence for IPC pumps that are clinically indicated for lymphedema and CVI-CVU, there are many clinical studies which we will cite that prove clinical efficacy for these indications but were not included in these guidelines. In addition, the guideline contains inaccuracies. We will address these in our specific comments.

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Guidelines such as Milliman's play an important role in ensuring that clinicians and payers have information to *guide* treatment decisions for patients with lymphedema and CVI/CVU. With that in mind, the Alliance would like to provide your editorial team with the most relevant literature regarding lymphedema and CVI/CVU and respectfully request that Milliman adopt the following recommendations:

1. Promptly revise the current IPC Guidelines by dividing it into two sets—one for IPC pumps that have the clinical indications for DVT prophylaxis and one for IPC pumps to allow for use for patients with refractory lymphedema or nonhealing venous ulcers (CVI/CVU). We also recommend in our specific comments below that the revised MCG reflect that language in Medicare's national coverage determination for lymphedema and for the treatment of CVI with venous stasis ulcers. This will allow for use of IPC in appropriate lymphedema and chronic venous ulcer patients in keeping with clinical evidence and best practice.
2. Remove the current inaccurate guidelines from circulation and inform those entities who have a license (i.e., subscription) that new guidelines will be released shortly.
3. Convene a meeting with Alliance members to discuss these recommendations in person and answer any questions the editorial staff may have.

## ***Specific Comments***

Our specific comments refer to Milliman Guidelines® Ambulatory Care, 17th Edition.

Our comments include the following concerns:

1. MCG "Background" and "Criteria"
2. General information related to IPC use in treatment of lymphedema and CVI/CVU
3. MCG Guidelines related to Lymphedema Treatment
4. MCG Guidelines related to Chronic Venous Ulcer treatment

## ***1. Concerns with MCG "Background" and "Criteria"***

MCG "Background" states:

> *Intermittent pneumatic compression devices are used to administer pressure to prevent stasis to the involved extremity, with a pump set to deliver a prescribed amount of pressure intermittently through one of many forms of sleeves. The pump is used for several hours a day, and the patient often applies compression in the form of bandaging or a compression sleeve following a pump-down session. A course of treatment lasts from a few days to four weeks.*

MCG "Criteria" states:

> *For the prevention of deep venous thrombosis in the immobile patient, intermittent pneumatic compression is established and effective. Intermittent pneumatic compression alone has been shown to be effective in reducing deep venous thrombosis in a variety of surgical patients. A systematic review concluded that compression and pharmacology together decrease the risk of deep venous thrombosis and pulmonary embolism greater than either alone.*

## Alliance's comments:

MCG has placed all pneumatic compression devices in one category. By not recognizing that the information describing IPC in the guideline's "background" and in the "clinical indicators" sections are applicable to sequential compression devices used for mechanical DVT prophylaxis and not to IPC pumps used for lymphedema or CVI/CVU, the guidelines are often inaccurate and confusing. As an example, the "typical course of treatment" described under "Background" claims that "A course of treatment lasts from a few days to 4 weeks." This is incorrect, and the reference cited to substantiate this claim (Morris, Journal of Medical Engineering & Technology) does not state this in any part of its content. In fact, the "typical course of treatment" described by the Milliman reviewer seems to refer to pumps for DVT prophylaxis, which are used in the inpatient setting when pharmacologic prophylaxis is contraindicated or when combined prophylaxis using pharmacologic and mechanical prophylaxis is deemed warranted. Milliman does not address IPC pumps provided for home treatment of patients with chronic lymphedema and venous stasis ulcers

I have listed below the differences for DVT and IPC pumps, summarizing how the Center for Medicare and Medicaid Services (CMS) codes them for billing purposes and well as how the U.S. Food and Drug Administration clears them for indications and intended use.

### *Coding Differences*

CMS's contractor, the Pricing Data and Coding contractor (PDAC), and DMEMAC medical directors have categorized three types of IPC pumps in this manner:

1. IPCs used for the treatment of lymphedema and chronic venous insufficiency with ulcers are coded based upon the characteristics of the base device. The codes used are:

   - E0650 - PNEUMATIC COMPRESSOR, NON-SEGMENTAL HOME MODEL
   - E0651 - PNEUMATIC COMPRESSOR, SEGMENTAL HOME MODEL WITHOUT CALIBRATED GRADIENT PRESSURE
   - E0652 - PNEUMATIC COMPRESSOR, SEGMENTAL HOME MODEL WITH CALIBRATED GRADIENT PRESSURE

2. IPCs used for the treatment of arterial disease are coded:

   - E0675 - PNEUMATIC COMPRESSION DEVICE, HIGH PRESSURE, RAPID INFLATION/DEFLATION CYCLE,FOR ARTERIAL INSUFFICIENCY (UNILATERAL AND BILATERAL SYSTEM)

3. There are other types of IPCs that are often referred to as deep vein thrombosis (DVT) pumps, massage therapy pumps, post-surgical DVT preventative pumps, etc. (not all inclusive). These types of devices are coded:

   - E0676 - INTERMITTENT LIMB COMPRESSION DEVICE (INCLUDES ALL ACCESSORIES), NOT OTHERWISE SPECIFIED

*Differences in clinical indications and intended use*

The FDA clears pneumatic compression therapy systems for the following indications and intended uses:

1. **IPC pumps for DVT prophylaxis**. These IPC systems are used to prevent deep vein thrombosis, most generally in the intraoperative and immediate postoperative period in patients who are at risk. This IPC system is, in the vast majority of cases, applied in hospital by hospital staff, as a temporary therapy along with, or as an alternative to pharmacologic methods, until the patient is ambulatory. The IPC device operates continuously until prophylactic therapy is discontinued, usually upon resumption of ambulation.

2. **Venous and lymphatic IPC pumps.** These systems are FDA cleared for treating lymphedema and chronic venous insufficiency with venous stasis ulcers. Venous disease and lymphedema can be classified according to clinical severity, etiology, anatomy and pathophysiology. These patients often present with other comorbidities that contribute to the severity of their disease. IPC therapy is most generally applied in the home environment, by the patient or by a caregiver. As lymphedema and venous stasis are permanent, chronic conditions, patients will require lifetime IPC use to keep chronic lymphedema and venous stasis ulcers in a manageable state.

   The mechanism of action of IPC pumps used to treat venous stasis and lymphedema is different from IPC pumps used for DVT prevention. The prophylactic compressive massage applied by DVT pumps assumes that the patient's lymphatic and venous system is functional and healthy, and the only requirement is to increase vascular flow while the patient is immobile during and directly after surgery, or during hospitalization. In contrast, venous and lymphatic IPC pumps apply treatment to patients with abnormal, malfunctioning venous and lymphatic systems. Venous stasis and lymphedema are chronic disorders. These disorders typically present with accumulation of edema, skin changes, wounds, and fibrosis. Treatment of CVI/CVU and lymphedema therefore require pumps that are designed with a very different compression profile to address the impairment of the lymphatic or venous system, taking into consideration skin condition and resistance, amount of edema and patient tolerance. The treatment time and frequency also differ considerably. Treatments for CVI/CVU and lymphedema generally are for one or several hours daily for a lifetime, in contrast to the round the clock, short-term treatment applied by DVT pumps. The appliances used with IPC pumps for CVI/CVU and lymphedema often cover different areas of the extremity, encompassing the entire foot as well as the lower and sometimes upper, leg, in addition to the arm. The trunk and torso may be treated as well. The pumps for treatment of CVI/CVU and lymphedema are intended for operation by the patient at home and are designed for use by people with no medical training.

**Alliance's recommendations:**

The mode of compression and intended use for treatment of lymphedema and venous stasis are significantly different from the mode of compression and intended use for DVT prophylaxis. The indications, use environment, and treatment protocol are also significantly different.

Therefore, as stated above, we recommend the following:

1. Promptly revise the current IPC Guidelines by dividing it into two sets—one for IPC pumps that have the clinical indications for DVT prophylaxis and one for IPC pumps to allow for use for patients with refractory lymphedema or nonhealing venous ulcers (CVI/CVU). We also recommend in our specific comments below that the revised MCG reflect that language in Medicare's national coverage determination for lymphedema and for the treatment of CVI with venous stasis ulcers. This will allow for use of IPC in appropriate lymphedema and chronic venous ulcer patients in keeping with clinical evidence and best practice.
2. Remove the current inaccurate guidelines from circulation and inform those entities who have a license (i.e., subscription) that new guidelines will be released shortly.
3. Convene a meeting with Alliance members to discuss these recommendations in person and answer any questions the editorial staff may have.

The rest of our comments and recommendations address the concerns associated with misinformation and excluded studies, and our recommendations for inclusion of studies applicable to lymphedema and CVI-CVU.

## *2. General information related to IPC use in treatment of lymphedema and CVI- CVU*

It is important to establish that compression is well-accepted as a cornerstone of both lymphedema and CVI/CVU treatment.[1] When compression stockings are successful in reducing the lymphedema or healing the CVU in a relatively timely fashion, there is no need to add IPC to the treatment regimen. **However**, **the need for IPC comes into play, not just as an adjunct to successful standard compression therapy, but as a treatment option when compression stockings fail, as they do for a significant portion of patients**. Raju, et al., in a study of over 3000 patients found that only 21% of the patients reported using compression stockings on a daily basis; 63% did not use stockings at all or abandoned them after a trial period for a number of reasons. Noncompliance is a major cause of failure, as compression stockings are notoriously difficult to don, and also difficult for some to tolerate. Stockings are inapplicable to about a quarter of patients due to condition of the limb or patient health. For another subset of patients, compression stockings are simply ineffective despite compliance.[2] **Compression delivered via IPC is, and has long been, a viable compressive alternative when other forms of**

[1] Comerota AJ. Intermittent pneumatic compression: physiologic and clinical basis to improve management of venous leg ulcers. *J Vasc Surg* 2011; 53:1121-9.
[2] Raju S, Hollis K, Neglen P. Use of compression stockings in chronic venous disease: patient compliance and efficacy. *Ann Vasc Surg.* 2007; 21:790-795.

**compression are not sufficient or not an option, and is appropriate after a suitable trial of conservative therapy (compression stocking, bandaging, etc.).**

## 3. ***Concerns with Milliman Guidelines: IPC in Lymphedema Treatment***

The Alliance was very surprised by, and strongly disagrees with, Milliman's position that use of IPC for lymphedema treatment is "inappropriate." Medical practitioners have successfully used IPC for treatment of lymphedema for decades. CMS's medical policies are evidence-based, and have covered and paid for IPC devices in their lymphedema coverage policies since the 1990s. While the research supporting IPC for lymphedema is not overwhelmingly robust compared with the large industry-funded studies in support of pumps for DVT prophylaxis, this comparison certainly does not warrant the designation of "inappropriate use."

The Alliance agrees with the concept of using *best available* evidence to create guidelines. With that in mind, it is important to acknowledge the well-established fact that the evidence base for ***any*** lymphedema treatment, including IPC, is less than robust. Lymphedema is misunderstood, under-researched, under-diagnosed and undertreated.[3,4] Large randomized controlled studies simply do not exist for lymphedema treatments (not just IPC). This was clearly described in the comprehensive 2010 AHRQ Technology Assessment-Diagnosis and Treatment of Secondary Lymphedema, which evaluated all lymphedema treatments, and concluded:

> *"…there is no evidence to suggest an optimal diagnostic testing protocol, an optimal frequency or duration of treatment, the most efficacious treatment combinations (including the use of maintenance therapy), the length of time for which persons should be tested or treated for lymphedema, and whether certain tests or treatments may benefit some types of patients more than others…."*[5]

The dearth of evidence for treating this condition is unfortunate, and is caused in part by the high degree of variability inherent in lymphatic and venous disease, as well as the preponderance of comorbidities related to these disorders and the difficulty of conducting such studies in a home care population. The lack of evidence is certainly a travesty for these patients. But all treatments cannot and must not be eliminated from use due to lack of high level evidence. Regardless of the state of the research, these patients must be treated, and that treatment is based on the best knowledge available.

### *a. MCG references do not support the conclusion that IPC is inappropriate for lymphedema treatment.*

[3] Rockson SG. The unique biology of lymphatic edema. Lymphatic Research and Biology 2009; 7(2):97-100. "It is becoming increasingly acknowledged that lymphedema is a chronic debilitating disease that is frequently misdiagnosed, treated too late, or not treated at all.

[4] Granger DN, Skeff KM, Chaite W, Rockson SG. Lymphatic biology and disease: Is it being taught? Who is listening? Lymphatic Research and Biology 2004; 2(2): 86-97

[5] AHRQ Tech Assessment on Secondary Lymphedema available at http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id66aTA.pdf

The limited references cited by Milliman are not representative of the body of literature that currently exists, and the references are not supportive of the conclusion that IPC is "inappropriate" for lymphedema treatment.

*Milliman's position: "For lymphedema, a systematic review concluded that intermittent pneumatic compression may have short-term benefit, but further studies are needed to determine the long-term benefit and impact.**(8)** (EG 1) A randomized controlled study compared 2 sleeve types and various compression cycles for 57 women with post-mastectomy lymphedema and concluded that there was significant improvement in lymphedema, and no difference between intervention protocols.**(9)** (EG 1) A consensus document cautions against intermittent pneumatic compression for lymphedema due to increased risk of proximal edema or fibrosclerotic ring development. **(10)** (EG 2)"*

- **Devoogdt, et al. (Milliman Ref #8):** The referenced article by Devoogdt, which is limited to breast cancer-related lymphedema, certainly does not justify Milliman's position that IPC is inappropriate for use in lymphedema treatment. Rather the article notes that, "**Intermittent Pneumatic Compression is effective, but once the treatment is interrupted, the lymphedema volume increases."** This statement does not indicate a lack of effectiveness. Rather, it underscores the need for continued therapy. This is especially important in cases of chronic venous insufficiency and lymphedema, for which there is no permanent cure. A parallel example would be insulin used by diabetics. Insulin use is effective, but must be used according to a prescribed ongoing schedule, and if interrupted, the patient's condition will worsen. The article also does not address the effects of treatment interruption on other lymphedema therapies. It also, on its own, does not adequately inform on appropriate treatment for chronic lymphedema and is not a definitive source for assessment of IPC in lymphedema treatment.

- **Pilch, et al. (Milliman Ref #9)** The Pilch study is a randomized controlled trial rated as "poor" in quality by the Technology Assessment on Lymphedema commissioned by the Agency for Healthcare Research and Quality in 2010. Clearly a study with this quality level **cannot** be independently relied upon to guide appropriate use of IPC. However, Milliman's citation of this reference stands in direct contrast to Milliman's conclusion that IPCs are inappropriate lymphedema treatment. **In fact, the study concluded that both IPC pumps studied demonstrated significant lymphedema improvement.**

- **ISL Consensus Document (Milliman Ref #10):** Likewise, the 2009 Consensus Document of the International Society of Lymphology **does not state in any way that IPC is inappropriate for use in lymphedema treatment,** nor does it "caution against intermittent pneumatic compression for lymphedema," The Milliman statement is incorrect and misleading.. The ISL does caution that intermittent pneumatic compression for lymphedema may increase risk of proximal edema or fibrosclerotic ring development at the top of the limb sleeve and that the treated area should be monitored carefully. However, the fact that the ISL mentioned the need for observation to avoid a potential complication (one that is not wholly accepted as fact by some lymphologists) certainly must not be misconstrued to imply that the ISL stated that IPC use is inappropriate. That would appear to be a misstatement of ISL's intention. The ISL also clearly states at the beginning of the document that NO lymphedema

treatment options had sufficient meta-analysis, much less rigorous, randomized, controlled studies to support them. This lack of evidence was a basis for developing a Consensus Document to guide clinicians based on best available knowledge, no justification for eliminating access to needed therapy options.

### *b. Literature to be considered with regard to IPC use in lymphedema treatment*

We appreciate the opportunity to provide expert literature to supplement Milliman's references. The following provides current information on IPC definitions, mechanisms of action, clinical indications and appropriate use, as well as effectiveness; clearly this demonstrates that IPC is a well-established, successful home treatment option and definitely not "inappropriate" for use in lymphedema treatment. We encourage the thorough review of the following information:

- *The National Lymphedema Network (NLN) Medical Advisory Committee provided an updated Position Statement in February 2011.*[6] *"IPC, also known as compression pump therapy, can be useful in some patients as an adjunct to Phase I CDT or a necessary component of a successful home program." The position paper notes that it is important to insure safe selection of the proper [pneumatic] device and appropriateness of IPC. The prescription must include the intensity of pressure and pattern of pressure needed, taking into consideration several aspects of the patient's situation including determination of need for programmable pressure to treat fibrotic areas, address treatment of ulcers, and adjust for patient's level of pain and skin sensitivity. If trunk, chest or genital swelling is present, the physician must determine whether a pump that provides appliances to treat those areas is necessary or if the patient can manage the trunk swelling through self-MLD or garments. If a pump with only extremity attachments [traditional pump] is used, close monitoring should be instituted to detect an increase in edema or fibrotic (hard) tissue above the device sleeve, called a fibrosclerotic ring.*

- *Society of Vascular Medicine*[7] "*One of the home treatment modalities we rely upon is use of pneumatic compression devices which we have found through our experience has given appropriate patients clinically meaningful improved health outcomes.* ***Like other successful modalities that have been used for years, pneumatic compression pumps have significant role in treating lymphedema but have not had robust level 1 evidence development. With that understanding, clinicians must base treatment, on the combination of existing evidence, underlying physiology, expert opinion and practice experience to develop practice standards and deliver the best level of care.***
  *Pneumatic compression devices have been part of the lymphedema treatment armamentarium for well over 20 years. We use pump therapy as an adjunct to the home care program for patients, including those of Medicare age, who are unable to manage their condition with compression bandaging and garments and self-massage. Certainly the*

[6] Position Statement of the National Lymphedema Network. Topic: *The diagnosis and treatment of lymphedema*. Updated February 2011. www.lymphnet.org.
[7] 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

*evidence exists that they produce clinically meaningful outcomes, and we have seen those outcomes ourselves."*

Many pneumatic compression device studies have demonstrated positive limb reductions. Such as:

- One study (Szuba[8]) demonstrated clear additional reduction achieved by adjunctive pneumatic compression added to complete decongestive therapy techniques.
- A controlled trial (Richmand[9]) utilizing IPC as a reduction modality showed a decrease in limb circumference of 45% to 47%.
- A prospective, randomized crossover study (Wilburn[10]) comparing IPC to self-massage showed significant reductions in arm volume after IPC but not after self-massage (a modality noted in the Milliman Guidelines' Alternatives to Procedure).
- A randomized trial (Johansson[11]) compared pneumatic compression to manual lymph drainage and a compression sleeve, and found that both methods significantly decreased limb volume, with no significant difference between the two treatment methods.

In addition to these and other clinical trials, laboratory and imaging studies clearly show the physiological effects of IPC in patients with lymphedema. Two separate studies (Partsch 1980, Baulieu[12,13]) demonstrate IPC treatment increased uptake and transport of radio colloid and labeled proteins into; through the lymphatics of lymph edematous extremities. A 2011 publication[14] clearly shows how IPC moves lymphatic fluid from the distal to proximal limb. A 2010 study provides direct evidence of lymphatic function improvement associated with the use of an advanced IPC device.[15]

### c. ***Alliance Recommendations:***

The evidence supports use of IPC in lymphedema treatment when standard forms of compression have failed to control the condition. We recommend that Milliman's guidelines reflect the Medicare national coverage determination for the use of IPC in lymphedema as stated below: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225&ncdver=1&DocID=280.6&SearchType=Advanced&bc=IAAAABAAAAAA&

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[8] Szuba A, Achalu R, Rockson SG. Decongestive lymphatic therapy for patients with breast carcinoma-associated lymphedema. A randomized, prospective study of a role for adjunctive intermittent pneumatic compression. Cancer 2002;95(11):2260-7

[9] Richmand DM, O'Donnell RF Jr, Zelikovski A. Sequential pneumatic compression for lymphedema. A controlled trial. Arch Surg 1985 Oct; 120(10): 1116-1119.

[10] Wilburn O, Wilburn P, Rockson SG. A pilot, prospective evaluation of a novel alternative for maintenance therapy of breast cancer-associated lymphedema [ISRCTN76522412]. *BMC Cancer* 2006l 6:84.

[11] Johansson K, Lie E, Ekdahl C, Lindfelt J. A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema. Lymphology 1998 (31): 56-64.

[12] Partsch H. Mostbeck A. Leitner G. Experimental studies on the efficacy of pressure wave massage (LymphaPress) in lymphedema. Z. Lympol. 1981 Jul; 5(1): 35-9

[13] Baulieu F, Baulieu JL. VaillantL. Secchi V. Barsotti J. Factorial analysis in radionuclide lymphography; assessment of the effects of sequential pneumatic compression. Lymphology. 189 Dec; 22(4): 178-85

[14] Olszewski WL, Cwikla J, Zaleska M, Domaszewska-Szosetk A, Gradalski T, Szopinska S. Pathways of lymph and tissue fluid flow during intermittent pneumatic massage of lower limbs with obstructive lymphedema. Lymphology 2011:44(2)54-64

[15] 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* August 2010; Vol. 1, No 1; 114-125

*Which states:*

> *Pneumatic devices are covered for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers.*
>
> *A - Lymphedema*
> *Lymphedema is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. The accumulation of lymph fluid results from impairment to the normal clearing function of the lymphatic system and/or from an excessive production of lymph. Lymphedema is divided into two broad classes according to etiology. Primary lymphedema is a relatively uncommon, chronic condition which may be due to such causes as Milroy's Disease or congenital anomalies. Secondary lymphedema, which is much more common, results from the destruction of or damage to formerly functioning lymphatic channels, such as surgical removal of lymph nodes or post radiation fibrosis, among other causes.*
> *Pneumatic compression devices 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. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.*

## *4. Concerns with Milliman Guidelines: IPC in Treatment of Chronic Venous Ulcers*

The Alliance was frankly taken aback that the MCG indicates that IPC use in treatment of nonhealing venous ulcers is "inappropriate", and further disturbed that Milliman referenced the Comerota publication as support for its position.

IPC has played a valuable role in supporting effective CVU home treatment for decades. The devices available on the market offer various designs and features, but all share the common trait of providing effective limb compression, which is the cornerstone of successful CVU treatment. All venous ulcers, and the associated patient suffering, outpatient visits, inpatient hospitalizations, and costs arise from sustained venous hypertension. Provision of adequate external compression has always been, and will remain, the key physiologic intervention that sustains leg and skin health. For patients for whom other forms of compression are intolerable or are not an option due to co-morbidities, or when these other forms of compression have failed, IPC offers an effective compressive treatment alternative. **The evidence is clear that extrinsic compression, as applied by IPC, is most certainly <u>not</u> "inappropriate" – it is medically necessary for some patients. As stated below, IPC therapy for CVU is an intervention with a proven record of efficacy.**

### *a. Milliman's references do not support conclusion that IPC is inappropriate for treatment of nonhealing venous ulcers.*

*Milliman's position: For venous ulcers, a systematic review concluded that intermittent pneumatic compression may increase venous ulcer healing when compared with no compression, but it is not clear whether it increases healing when added to treatment with bandages, or if it can be used instead of compression bandages or garments. (**1**) (EG1) Proper prescription of intermittent pneumatic compression for venous ulcers requires further definition. (**4**)(EG2) Further rigorously controlled trials are required to determine whether intermittent pneumatic compression increases the healing of venous ulcers when used in contemporary practice where compression therapy is widely used. (**1**)(**4**)(EG1).*

**Comerota**[16] **(Milliman Ref #4) The** Alliance is extremely troubled by Milliman's characterization of the Comerota article; after thorough review of this article, it is difficult to discern how one could presume to correlate the article's findings to the negative statements attributed to Comerota' s publication by the Milliman Guidelines. In fact, what Comerota concluded is: *"The effects of IPC observed in patients with venous ulceration alter the underlying pathophysiology, producing an environment compatible with ulcer healing. Effects such as increased venous return, reduced leg edema, increased endogenous fibrinolysis, reduced intravascular coagulation, and improved arterial (skin) perfusion resulting in increased venous return, reduced leg edema, increased endogenous fibrinolysis, reduced intravascular coagulation, and improved arterial (skin) perfusion resulting in increased $TcPO_2$ combine to alter the wound environment in favor of healing. Therefore, it should not be surprising that well-designed clinical studies evaluating IPC added to standard wound care and compression therapy show improved rates of ulcer healing….**An overview of the literature suggests IPC speeds healing and increases the number of VLUs healed by providing an environment favorable to wound healing."* This conclusion does not support Milliman's position that IPC use is "inappropriate" for venous ulcer treatment; in fact, it directly contradicts it.

**Cochrane [17](Milliman Ref #1) Milliman** appears to rely on a 2011 Cochrane Review as a primary basis for its IPC Guidelines. We agree that the Cochrane Collaboration is a well-respected organization and as practitioners we value the reviews as <u>one</u> source of high level evidence. The Cochrane mission itself acknowledges that these reviews serve merely as one component of the evidence base. These reviews were never intended, nor should they serve, as the major component of the coverage evaluation process, just as they cannot define ideal bedside clinical decision making. Such systematic reviews and meta-analyses provide net treatment effects for subjects randomized within a very small number of clinical trials. **The trials included in the Cochrane review do not provide enough data for either indiscriminate use *or* for complete elimination of use of this well-established treatment option.**

The Cochrane review does acknowledge that IPC increases venous ulcer healing rates when compared with a wound dressing alone, but concludes "this finding is not applicable to the

[16] Comerota AJ. Intermittent pneumatic compression: physiologic and clinical basis to improve management of venous leg ulcers. *J Vasc Surg* 2011; 53:1121-9.

[17] Nelson EA, Mani R, Thomas K, Vowden K. Intermittent pneumatic compression for treating venous leg ulcers. Cochrane Database of Systematic Reviews 2011, Issue 2. Art No.:CD001899.

majority of modern settings where compression bandaging is widely used and effective." We are certain that this conclusion is overstated. Compression bandaging is indeed effective when applied correctly and consistently. But a significant fraction of CVI/VSU patients may not have access to compressive bandaging; or are not candidates for compressive bandaging or stockings; or cannot apply them; or are not successful with this form of compression. For all of these patients, their care is better and outcomes are superior using IPC in addition to wound dressings, rather than going without any other compression therapy. **When standard compression is not a viable treatment option for a CVI/VSU patient, IPC often represents the only practical compression alternative.**

The Alliance concludes from the studies reviewed by Cochrane that IPC is efficacious, but that the evidence base does not support indiscriminate coverage of IPC for VSU. **We believe that this Cochrane review cannot be interpreted to support the conclusion that IPC is "inappropriate" as a treatment option for all CVI/VSU patients**.

### *b. Literature to be considered with regard to IPC use in CVI/VSU treatment*

Other systematic review and published studies: We are surprised that Milliman failed to consider the review done by Berliner[18] (which is the basis for Medicare's coverage policy and which evaluates many of the same studies as Cochrane but arrives at a considerably different conclusion). Berliner's conclusion: *"Compression therapy is an important part of treatment for CVI and venous leg ulcers. Often patients do not comply with compression therapies…because of difficulty with use of the therapies.* ***Long term use of pneumatic compression devices in the home environment is an effective alternative to other compression therapies for patients who are unable to or refuse to comply with other methods****. "*

Guidelines for the treatment of venous ulcers[19] published by an advisory panel of academicians, private practice physicians, and other medical professionals states: "IPC can be used with or without compression dressings and can provide another option in patients who cannot or will not use an adequate compression dressing system." The advisory panel notes that the guideline level for this statement is Level 1: "Meta-analysis of multiple RCT's or at least two RCTs support the intervention." The guideline continues, "Intermittent pressure stimulates venous return and can be utilized when constant compression is not tolerated."

A recent 52-patient, 96-week study[20] of hard-to-heal venous ulcers compared IPC + standard compression to compression therapy (control) alone. The median time to wound closure by 9 months was 141 days for the IPC group and 211 days for the control group and daily wound healing rate was significantly faster for the IPC group. Clearly IPC is a valuable treatment component for some CVI/VSU patients.

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[18] Berliner E, Ozbilgin B, Zarin DA. A systematic review of pneumatic compression for treatment of chronic venous insufficiency and venous ulcers. *J* Vasc Surg 2003;37:539-44

[19] Robson MC, Cooper DM, Aslam R, Gould LJ, Harding KG, Margolis DJ, Ochs DE, Serena TD, Snyder RJ, Steed DL, Thomas DR, Wiersma-Bryant L. Guidelines for the treatment of venous ulcers. Wound Rep Reg 2006; 14; 649-662.

[20] Alvarez O, et al. Effectiveness of intermittent pneumatic compression for the treatment of venous ulcers in subjects with secondary (acquired) lymphedema. *Vein* 2012; 1(5)

Immobile CVI/VSU patients are another population for whom IPC may be the most appropriate compressive therapy. Partsch notes that conventional compression is ineffective in immobile patients because the standard compression relies upon static pressure against an active calf-muscle pump to augment venous and lymphatic return. In immobile patients, the change in muscle tone activated by standing or ambulating is not possible due to inability of the patient to perform the physical movements. IPC not only applies required pressure to the leg, but also mimic rhythmic muscle contractions, augmenting the veno-lymphatic pump.[21] Milic et al. found significant association between the failure of CVU to heal within 1 year and the CAC (calf: ankle circumference) ration less than 1.3 and a fixed ankle joint with reduced ankle ROM. Short walking distance (<200 meters) was also an indicator of slow healing. **The findings led to conclusion that impairment of the calf muscle pump is associated with non-healing venous ulcers, and that "[i]t may be prudent to introduce intermittent pneumatic compression in the treatment of these patients in order to stimulate muscle pump and to improve ulcer healing**."[22]

Physiological effects of pneumatic compression: The physiological mechanisms of action produced by pneumatic compression are the core of efficacious treatment of CVU. IPC has been shown, without controversy, to generate hemodynamic and hematologic effects which create a favorable healing environment and increased CVU healing. Decades of research verify that IPC reduces venous stasis and increase flow velocity in the deep veins, decreasing venous pressure, inflammation, and interstitial edema. Pneumatic compression treatment positively alters the wound environment through increased fibrinolytic activity, reduced intravascular coagulation and improved arterial perfusion. [23, 24]

Beyond the physiologic mandate to provide venous compression, we note that clinical practice standards, and reimbursement standards, have long sustained IPC use. Medicare first began coverage of IPC for this indication in 1986 and continues to cover IPC use for CVU that remain unhealed for greater than 6 months. We note, as well, that other major insurers (Ex: Aetna, CIGNA, and Humana) cover IPC for nonhealing CVU, recognizing that these patients have few home treatment options. **This widespread acknowledgement (extending from the evidence, including physician and clinician professional societies) that IPC should be available to an appropriate cohort of CVU patients supports our conviction that the Milliman Guidelines for IPC are inconsistent with best available clinical knowledge.**

## ***C. Alliance Recommendations:***

The evidence supports use of IPC in CVU treatment when standard forms of compression have been utilized for 6 months and the wound remains unhealed. As stated earlier in our comments in regards to lymphedema, we recommend that Milliman's guidelines reflect the same Medicare national coverage determination which also includes CVI with venous stasis ulcers:

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[21] Partsch H. Intermittent pneumatic compression in immobile patients. *Int Wound J* 2008; 5:389-97.

[22] Milic DJ, Zivic SS, Bogdanovich DC, Karanovic ND, Golubovic ZV. Risk factors related to the failure of venous leg ulcers to heal with compression treatment. *J Vasc Surg* 2009;49:1242-7.

[23] Comerota AJ. Intermittent pneumatic compression: physiologic and clinical basis to improve management of venous leg ulcers. *J Vasc Surg* 2011;53:1121-9

[24] Chen AH, Frangos SG, Kilaru S, Sumpio BE, Intermittent pneumatic compression devices-physiological mechanisms of action. Eur *J Vasc Endovasc Surg* 2001; 21:383-392.

http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225&ncdver=1&DocID=280.6&SearchType=Advanced&bc=IAAAABAAAAAA&

Which states:

> *Pneumatic devices are covered for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers.*
> *B - Chronic Venous Insufficiency With Venous Stasis Ulcers*
> *Chronic venous insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers.*
> *Pneumatic compression 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.*

## Conclusion

**Patients with lymphedema or CVU universally require access to effective compression; when conventional compression is not an option, IPC often represents the only treatment option**. If treatment for these conditions was based on Milliman's current guidelines, then a substantial population of patients would be without a viable form of compression. This would result in the following: a progression of ulcers and cellulitis for the patients with ensuing hospitalizations, thus increasing morbidity and costs. The withdrawal of a proven, non-experimental treatment will worsen suffering and health care costs.

The evidence base fully supports use of IPC as either a primary lymphedema or CVU treatment for individuals in whom other compressive therapies cannot be applied or when standard forms of compression are ineffective.

The Alliance recommends that Milliman take seriously our set of recommendations:

1. Promptly revise the current IPC Guidelines by dividing it into two sets—one for IPC pumps that have the clinical indications for DVT prophylaxis and one for IPC pumps to allow for use for patients with refractory lymphedema or nonhealing venous ulcers (CVI/CVU). We also recommended in our specific comments that the revised MCG reflect that language in Medicare's national coverage determination for lymphedema and for the treatment of CVI with venous stasis ulcers. This will allow for use of IPC in appropriate lymphedema and chronic venous ulcer patients in keeping with clinical evidence and best practice.
2. Remove the current inaccurate guidelines from circulation and inform those entities who have a license (i.e., subscription) that new guidelines will be released shortly.
3. Convene a meeting with Alliance members to discuss these recommendations in person and answer any questions the editorial staff may have.

The Alliance welcomes the opportunity to serve as a resource to you and your staff as you review this document and when revising the guidelines for this important therapy.

Sincerely,

Marcia Nusgart, R.Ph.
Executive Director