ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

December 30, 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,

We wanted to thank you for your email and letter dated November 26th 2013 and apologize for the delay in responding to you. As the Board of Directors for the Alliance of Wound Care Stakeholder's ("Alliance"), we have reviewed your letter and shared this with our members who still have grave concerns about the inaccuracy of the current version of the guidelines and the serious impact on patients who need access to these devices.

It is our understanding from your letter that the information we have previously provided is being evaluated by your editorial team in preparation for the next edition of the MCG for Intermittent Pneumatic Compression (IPC). However, we want to ensure that certain key points are clear and are considered by your team so that the next edition accurately reflects the status of the evidence base that currently informs use of Intermittent Pneumatic Compression in lymphedema and chronic venous ulcers. Since the most well respected clinical experts in lymphedema and chronic venous ulcers are members of the Alliance, we would be happy to have some of them serve as a resource to you to review the next edition of the MCG on this subject to ensure that they are in alignment with current clinical practice and research in this area.

Since the MCG are respected and well-established as an expert resource in the insurance industry, we know that they are being used as the main and even only resource for numerous insurance providers on which they base coverage decisions. Despite your position that the *"guidelines do not determine the appropriateness of care for any specific patient…the guidelines are not intended as a substitute for this important professional judgment,"* it is well-known that the Guidelines are used in many cases to deny a device that a treating physician has prescribed as the appropriate treatment for a patient's condition. We have attached many examples that illustrate this from various insurance companies. (Exhibits A and B).Therefore, while this may not be your intention, the fact is that for all practical purposes, these MCG are indeed relied upon as an expert clinical resource by your insurance company customers to make **the final decision** regarding whether treatment recommended by the physician is covered by the payer. This has the effect of denying care for the patient, which is often in direct opposition to the patient's physician's professional judgment. This is **having a very real and very negative impact** on the ability of lymphedema and venous ulcer patients to obtain access to treatment which their practitioners believe is medically necessary and for which there is medical evidence to support its use.

As a clinical association that includes many of the nation's experts on lymphedema and venous ulcers, the Alliance strongly submits that the issue that must be acknowledged and addressed by MCG due to the fact that

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this Guideline - and resulting clinical decisions - are based on incomplete evidence base and provide inaccurate information in the Guideline's "Criteria" "Inappropriate Use" and "Clinical Indications for Procedure" sections. We understand it can be challenging to undertake development of appropriate guidelines for the myriad conditions that MCG endeavors to provide. As experts in lymphatic and venous disease, we believe it is our responsibility to assist in providing accurate, complete and current information on the conditions and treatments. Much of that information was provided in our previous letter to you in July 2013. We do wish to reiterate some of those points and use examples to illustrate the real-world impact of misuse of the Guidelines by insurers.

Criteria Section of MCG for IPC

MCG states that IPC is used for "prevention of deep vein thrombosis in the **immobile** patient." We agree that DVT prophylaxis is obviously a concern as approximately 100,000 Americans each year die from DVT complications. But that type of compression, which is described by HCPCS code E0676, has very different characteristics than the IPC devices used for lymphedema and venous ulcers, which fall under codes E0651 and E0652. **It is inappropriate to group these types of compression in one guideline because their audiences and clinical applications should not be confused, as is currently occurring.**

This confusion is illustrated by the fact that patients across the country with lymphedema and venous ulcers are being denied by insurers who interpret this guideline as stating that if the patient is not immobile then the device is never medically necessary, which of course is incorrect. The attached rejection letter (Exhibit A) from Unite Health Care (UHC), for a patient who desperately needs IPC, clearly illustrates the end results of the current MCG and why we are advocating so hard for a change.

UHC specifically references MCG 17th Edition in this rejection letter and states *"This device is approved for members who cannot walk. We do not see that you are unable to walk".* Your payer customer used **no** clinical judgment or assessment of the individual patient need. It merely used a word from the "criteria" section of your guideline to support denial. We recognize that you cannot control the payer's use of the Guideline. However, by revising the Guideline to accurately reflect how IPC is used for lymphedema and venous ulcers, MCG can minimize these negative and erroneous interpretations.

Lymphedema and venous ulcer patients are normally able to walk but struggle with numerous other impairments including pain, impaired range of motion, significant risk of infection and impaired quality of life both physically and psychosocially. Through the use of Intermittent Pneumatic Compression, a patient with lymphedema or nonhealing venous ulcers experience dramatic improvement in their conditions that they often cannot achieve with bandaging alone. The evidence base supports this, and patients who fail conservative treatment must have access to IPC to control these serious conditions.

Inappropriate Use Section of MCG for IPC

The Guideline specifically (and incorrectly) calls out lymphedema and venous ulcers in the "Inappropriate Use" section. In your email/letter you stated *that "…mention of a specific diagnosis or topic in this [Evidence] section does not make the determination that it would be inappropriate to use a device for a specific patient situation."* However, the fact that the Guideline clearly calls out these two diagnoses as "inappropriate use"

contradicts your statement. Payers are definitely basing denials on the "Inappropriate Use" section. See attached denial letter (Exhibit B) from UMR for a young woman with hereditary lymphedema that states:

> *"Per MCG ACG: A-0340 Intermittent Pneumatic Compression with Extremity Pump, the use of this device for lymphedema is unproven. It is listed in the 'Inappropriate Use' section."*

This patient is being denied access to a medically necessary, prescribed therapy for a lifelong condition based on the MCG. Again, **no** clinical judgment or consideration of the individual patient's condition or well-being was considered. Some insurers, despite being provided with significant clinical information outlining the patient's need and severe clinical condition, have quoted the MCG at three consecutive levels of appeal as the basis for denial. This misuse of the Guideline only serves to bolster our strong belief that there is significant responsibility that goes with publication of guidelines, and we wish to assist in remedying inaccuracies.

To further illustrate the confusion and misuse of the Guidelines we have attached as Exhibit C a copy of the Health Plan of Nevada, a United Health Care Company. In this policy regarding reimbursement for Pneumatic Compression Devices, you will see direct references from the MCG. Indeed, their "Commercial Coverage Rationale" uses MCG's wording exactly, listing lymphedema and venous stasis ulcers as "inappropriate use." However, further down in the same document, in the section "Medicare & Medicaid Coverage Rationale," this policy quotes from the Center for Medicare and Medicaid Services National Coverage Determination, in which it is clearly stated that "Pneumatic devices are covered for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers." Therefore, this same policy document includes MCG's statement that treatment for lymphedema and venous stasis ulcers constitutes "inappropriate use," and right below it, a statement from the Centers for Medicare and Medicaid Services that lymphedema pumps ARE covered for these same exact uses. This constitutes a considerable discrepancy between Center for Medicare and Medicaid Service's carefully considered evaluation of the available evidence on the efficacy of lymphedema pumps, and MCG's evaluation of the same body of evidence.

As was discussed in the Alliance's letter to you dated July 18, 2013, IPC is most definitely not "inappropriate" in the treatment of either lymphedema or nonhealing venous ulcers. There is sufficient evidence to support IPC use in both of these conditions. In fact, new research demonstrating the efficacy of IPC in lymphedema treatment has been published since our July letter. These are:

- 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.

- Eric J. Lullove DPM and Oscar M. Alvarez PhD have just completed their study, **Improvement in Clinical Outcomes, Physical Function, and Bodily Pain Following a 12 Week Course of Intermittent Pneumatic Compression (IPC) Therapy in Patients with Chronic Venous Ulcers: Results of an Observational Longitudinal Retrospective Study** whose abstract (below) will be presented at the 2014 Spring Symposium on Advanced Wound Care. The study has been submitted for publication and will be published shortly.

ABSTRACT
Background: *Clinical records of 94 chronic venous ulcer patients (treated at 2 independent specialty centers) were included in a retrospective analysis to evaluate the effects of standard of care plus continued IPC therapy during and after wound closure.* ***Methods:*** *Both clinical centers employed the Venous Clinical Severity Score (VCSS) to monitor clinical outcomes. One center also measured quality of life (QOL) outcomes using the SF-12 Health Survey (n=34). IPC application varied slightly between the 2 clinical sites. One Wound Care Center in South Florida treated patients (n=60) using a 4 chamber gradient IPC at 50mmHg for 45 minutes BID (5days on and 2 days off). The other Center in New York treated patients (n=34) with a 4 chamber gradient IPC at 55mmHg for 1 hour BID. Both Wound Care Centers applied IPC therapy using standard adjustable (95.3cm) half leg sleeves. Both Centers used the same IPC therapy pump (Bio Compression Model 2004, Bio Compression Systems Inc. Moonachie, NJ). All patients were seen weekly for standard evaluations and reapplication of compression bandages. Patient record analysis was for 12 consecutive weeks beginning at baseline (prior to IPC application). VCSS scores were recorded at monthly intervals.* ***Results:*** *The incidence of ulcer healing was 80% after 12 weeks of IPC therapy. Symptomatic improvement was noted in every VCSS parameter measured. In the category of pain there were statistically significant differences in number of patients reporting severe pain ($p=0.004$) and a highly significant difference in the number of patients reporting no pain after 12 weeks of IPC therapy ($p<0.001$). In the category of edema significant improvement was noted after 12 weeks of IPC therapy in patients that had severe edema at baseline ($p=0.017$) and also in the number of patients where the edema resolved ($p=0.004$). Severe inflammation was significantly reduced in all study patients ($p=0.022$) and completely resolved in 60 of the 94 patients (63.8%, $p<0.001$). The overall combined physical and mental component scores were improved by 45% as a result of IPC therapy. Physical functioning improved by 79% after 12 weeks of IPC therapy ($p=0.041$). Bodily pain and vitality scores were on the average 2.1 fold greater after IPC therapy ($p<0.05$).****Conclusion:*** *The incidence of ulcer healing was 80% after 12 weeks of IPC therapy. Significant symptomatic improvement was noted in every VCSS parameter. IPC therapy resulted in significantly better physical function and improved QOL.*

The Alliance therefore respectfully requests that both lymphedema and venous ulcers be removed from the "inappropriate use" section as that designation is inaccurate and misleading.

Clinical Indications for Procedure Section of MCG for IPC

MCG says that"

"*Intermittent pneumatic compression with extremity pump may be indicated when* ***ALL*** *of the following are present:*

- *Deep venous thrombosis prevention for immobile patient*
- *No deep venous thrombosis*
- *No lower extremity arterial disease*
- *No skin disease of extremity*
- *No untreated cellulitis*

- *Absence of severe heart failure"*

In this section the MCG specifically placed the word "all" in bold and capitalized letters. First, this is problematic because it implies that there are no other clinical indications, which is untrue. Second, IPC is often used on patients with impaired skin integrity of the extremity; indeed by enhancing lymphatic and venous flow, skin disorders (hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers) are often much improved by IPC therapy. One of the criteria for coverage in Medicare policies, also identified in Exhibit C, is for chronic venous insufficiency with a venous ulcer. Therefore, the statement "no skin disease of extremity' needs to be removed from the Guideline.

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As stated in our examples above, we have found that insurance companies do reference and follow the MCG guidelines, not as a guide but, in direct contrast to statements made in your letter, as a definitive decision-making resource. We are deeply concerned about this direct result of patients not able to have access to treatment which their medical practitioners believe is medically necessary and for which there is medical evidence to support its use as demonstrated in our letter. The Alliance shares your mission and responsibility to ensure that patients with venous and lymphatic disorders are served appropriately. We provide this information in that spirit and will be pleased to discuss any facet of the evidence base or answer questions about appropriate use of IPC in lymphedema and venous ulcer treatment. As in our previous letter, we again request that the current guidelines be removed until the new revised version is available.

Thank you for your kind consideration of this information.

Sincerely,

The Board of the Alliance of Wound Care Stakeholders

Dr. Caroline Fife, Co-chair
Dr. John Steinberg, Co-chair
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Jule Crider, Board Member
Karen Ravitz, Board Member
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