ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

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Submitted electronically to PCDRecon@noridian.com

Re: DL33829 Proposed LCD Pneumatic Compression Devices

Dear Doctors Ballyamanda, Brennan, Hoover and Gurk,

On behalf of the Alliance of Wound Care Stakeholders, ("Alliance"), I am pleased to submit our comments on the proposed LCD DL33829 Pneumatic Compression Devices. The Alliance is a nonprofit multidisciplinary trade association of physician specialty societies, clinical and patient associations whose mission is to promote evidence-based quality care and access to products and services for people with chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. This letter was written with the advice of Alliance clinical specialty societies and organizations who not only possess expert knowledge in treating complex chronic wounds/ulcers, but also in wound care research. The Alliance is viewed as the umbrella association for all of wound care since our membership includes not only the clinical and patient associations mentioned but also wound care clinics and business entities (manufacturers and distributors). A list of our members can be found on our website: http://www.woundcarestakeholders.org/about/members

We have serious concerns with the conclusion of the proposed LCD which states "Since there is no clear evidence that IPC results in positive health outcomes in the Medicare-eligible population, IPC for the treatment of CLI will remain as not "reasonable and necessary" for purposes of Medicare reimbursement." First of all, many of our vascular and wound care medical specialty society members (e.g., Society for Vascular Medicine, American Professional Wound Care Association) state that there is adequate evidence of sufficient data generalizable to the Medicare population for the DMEMACs to provide coverage for EO675 ("Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency [unilateral or bilateral system]") for treatment of critical limb ischemia (CLI). They believe that treating Medicare beneficiaries with E0675

- Is safe, effective, reasonable and necessary to provide patients with a validated low risk option in the context of "no option" and associated marked increase for lower extremity amputation

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- Is a viable option to amputation where no other options are available and because all other options have been exhausted and or failed

We are in agreement with the points outlined in Dr. Mark Melin's DMEMAC comment letter that counter the reasons that the DMEMACs decided against coverage of these devices. We would appreciate that you review carefully their points regarding but not limited to: sample size, high probability of bias without sham controls and blinding, generalizability to the Medicare population, exclusion of co-morbities.

We appreciate your consideration of these comments and urge that the DMEMACs again provide coverage for E0675 for the treatment of patients with CLI for both the upper and lower extremities.

Sincerely,

Marcia Nusgart, R.Ph.
Executive Director