

Response to Comments to Accompany LCD for Pneumatic Compression Devices

- 1) Comment: Some commenters noted that the LCD should provide coverage for pneumatic compression devices (PCDs) to include those for peripheral arterial disease (PAD). Other commenters proposed limited PCD coverage for PAD.

Response: The medical directors disagree. When the DME Contractor Medical Directors published the Proposed LCD for PCDs in 2011, there had been a period of several years when we had regularly received requests for coverage of PCDs for PAD from a number of those treating these conditions, suggesting the technology and its acceptance had significantly advanced and was becoming more generally accepted. Many at the DME Open Public Meeting in August 2011 and in multiple written comments supported this position. Several commenters took the position that the LCD should include coverage of PCDs for *all* PAD, and not be restricted to those who would otherwise qualify for a surgery but were medically ineligible.

This final policy does not allow for coverage of PCDs for PAD of any severity. In more closely and serially reviewing the statements and guidelines from nearly all of the major cardiovascular and surgical societies, support for the use of this technology is not found, even for limited use. For this reason we are not at this time adding routine coverage for PCDs for PAD.

Continuing literature searches since the date of the draft release have shown no long-term studies supporting that outcomes using a PCD are comparable to the accepted standard of using a surgical revascularization where possible and no major cardiovascular or surgical societies have adopted guidelines taking this position. We received limited journal copies, anecdotal case-reports and brief series information to support the use of this technology as a temporizing or supportive measure for those with advanced disease who are otherwise ineligible for surgery, but here as well, there are no sizeable, long-term studies of efficacy. The medical directors extensively again reviewed all submitted literature as well as coverage decisions by major agencies, health service research entities and insurers (see in the LCD under **Sources of Information and Basis for Decision**). Of these, *only one*, from Ireland's Health Information and Quality Authority takes a position supporting any coverage, and that is equivocal, indicating "...more research is needed to confirm...a *potentially* beneficial treatment for people at risk of amputation who are not candidates for revascularization...remains unproven." After this reassessment, we have concluded it is not reasonable and necessary to add coverage of arterial compression devices (E0675) at this time.

- 2) Multiple commenters suggested diagnostic findings and tests that in their opinion could confirm eligible beneficiaries for PCDs for PAD as a possible alternative to attestation that the beneficiary would otherwise be a candidate for surgery.

Response: There was little consistency to these recommendations. Had we pursued coverage of arterial compression at this time, we would have needed to continue the "otherwise be a candidate for surgery" criterion. Currently, there is no consensus on the usefulness of available diagnostic tests to demonstrate the predictive value of arterial PCD.

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- 3) Several commenters recommended allowing coverage of an E0652 PCD for secondary lymphedema of any etiology, with or without ulcers, when diagnostic criteria are met and the E0650 or E0651 has been ineffective at controlling the lymphedema. It was recommended that documentation of trained and supported daily use of a carefully fitted E0650 or E0651 for a minimum of 4 weeks without significant clinical response should be sufficient to evidence the need for the E0652 device. It was recommended the documentation include a detailed description of the therapies recommended in conjunction with the pump as well as provide objective clinical details of why E0650/E0651 device and adjunct therapies were not effective.

Response: The CMS National Coverage Decision (280.6) has determined, “The only time that a segmented, calibrated gradient pneumatic compression device (HCPCs code E0652) would be covered is when the individual has unique characteristics 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.”

Review of the clinical literature indicates that the *only* consistently documented clinical need for an E0652 is for the treatment of lymphedema extending onto the chest, trunk and/or abdomen past the limits of a standard compression sleeve, where the lymphedema has failed to improve with a continued, carefully-performed, good-faith trial of the E0650/E0651 device coupled with other more conservative therapy.

Commenters indicated a need to use an E0652 where an E0650/E0651 was simply incapable of the task due to conditions of severe obesity, chronicity, fibrosis, number of wounds or other reasons, but there was no literature provided to enable a systematic way to identify these rare situations. The absence of such clinical literature prevents development of criteria to identify individual clinical circumstances and they must therefore continue to be addressed at appeal by individual consideration of a record which must establish that all other more conservative approaches including the continuous, regular use of E0650/E0651 over time have proven insufficient, whereas a trial of the E0652 has been successful.

- 4) Several commenters raised a concern that the draft LCD conflicts with NCD 280.6 for PCDs by being more restrictive than the NCD in the coverage afforded to causes of lymphedema.

Response: The revised LCD broadens the allowed indications and thereby specifically addresses any concern in this area. There is no conflict with the revised LCD and the NCD.

- 5) One commenter recommended that an inability to tolerate compression bandaging for venous ulcers should be an immediate indication for venous compression regardless of the length of time the ulcers have been present.

Response: This is not an option for the DME MACs under NCD 280.6.

- 6) One commenter recommended that the six-month period of conservative therapy for venous stasis ulcers be reduced to four months. Other commenters also objected to the six-month requirement.

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Response: This is not an option for the DME MACs under NCD 280.6.

- 7) Several commenters recommended that PCDs should be covered for chronic venous insufficiency even in the absence of ulcers.

Response: This is not an option for the DME MACs under NCD 280.6. However, the coverage of lymphedema from various causes has been broadened which will likely accomplish much of what these commenters desire.

- 8) One commenter felt the language “...has failed to improve with a period of at least four weeks of regular daily home use of the E0650 or E0651 with careful, in-person fitting, overview and training by a technician skilled in and regularly, successfully using the appliances prescribed..” is unclear.

Response: The language and formatting have been clarified.

- 9) One commenter recommended that an E0652 be allowed for unilateral limb edema, documented to be unresponsive to use of E0651/E0650 coupled with other more conservative measures, on a prior authorization basis.

Response: This recommendation is beyond the scope of the current LCD and Policy Article revisions.

- 10) One large manufacturer of PCDs recommended that part of the current focus in the NCD and LCD about usage of the E0650 and E0651 was because of price differential and that with improvements in technology and cost-efficiencies in recent years, Medicare should reduce the reimbursement for E0652 and relax requirements for use of this code.

Response: This recommendation is beyond the scope of the current LCD and Policy Article revisions.

- 11) Quite a number of commenters had recommendations and/or concerns about the rapidity and duration of inflation and deflation times for arterial compression devices, indicating these are critical variables in their functional efficacy and that a number of the products on the market seeking coverage do not have comparable functional efficacy. Others had concerns that the manufacturing requirements for arterial compression devices were not adequately addressed, including a number of very detailed and well-documented observations, reports of research on various parameters and peer-reviewed articles on these topics

Response: Coverage of arterial compression devices (E0675) is not being added at this time.

- 12) Multiple commenters objected to the requirement that the ordering of an E0675 was being restricted to a vascular surgeon.

Response: Coverage of arterial compression devices (E0675) is not being added at this time.

- 13) Several commenters pointed out that angiographic dye may be contraindicated in some patients and therefore alternative diagnostic methods for severity of arterial disease are necessary.

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- 14) Several commenters offered recommendations and/or concerns about the recertification of the need for PCDs for arterial compression.

Response: Coverage of arterial compression devices (E0675) is not being added at this time.

- 15) Several commenters indicated podiatrists should be an eligible provider type to order PCDs, rather than have ordering providers limited to physicians (MD, DO) and physician extenders (NP, PA & CNS). Specifically, in response to the proposed fall 2014 revision released in September 2014, intended to be effective 11/01/2014, it was pointed out by multiple stakeholders and societies, including representatives of the American Podiatric Medical Association, that the language of the LCD was more restrictive than many state scope of practice requirements.

Response: We agree. This was one of several important reasons for withdrawal of the proposed fall 2014 revision. The language has been changed to be specifically consistent with state scope of practice requirements.

- 16) One commenter indicated PCDs are very effective in his vascular surgery practice without needing to use or try more conservative measures first and on that basis they should be a first-line therapy for this condition.

Response: The Medical Directors disagree. Many therapies and testing modalities *may* be effective for conditions which would otherwise respond to simpler, conservative measures. The logic of medical necessity indicates that such interventions should be used in series, first using simpler measures shown by accepted clinical practice to often be effective, unless there is a clear evidence basis to skip these simpler measures for the specific clinical circumstances.

- 17) One commenter pointed out the word “endoscopic” should be changed on page four.

Response: We agree. The language has been changed.

- 18) Two commenters pointed out that the CMN for pneumatic compression pumps, CMS Form 846 (DME Form 04.04B), does not track with the NCD and LCD requirements which causes confusion in submitting claims.

Response: We agree, but this is currently beyond the scope of this LCD and Policy Article revision.

- 19) Several commenters pointed out that the proposed fall 2014 revision required a patient to present with “chronic and severe” lymphedema of 6 months duration before any potential qualification for PCD and that this is more restrictive than the NCD or draft LCD, which both require failure of 4 weeks conservative therapy and did not stratify by severity. Further the LCD did not define “severe” lymphedema nor did it refer to accepted lymphedema staging stratification.

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Response: The Medical Directors agree and acknowledge this was an error, one of the reasons for our withdrawal of the proposed fall 2014 revision, and we thank the several sources who brought this to our attention. This has been corrected and clarified in the current future LCD.

- 20) Commenters pointed out that the proposed fall 2014 revision required that conservative therapy “must include the component of Manual Lymphatic Drainage (MLD) which is more restrictive than the NCD.”

Response: The language has been changed to reinforce the current clear standard of care that MLD should be used and taught for self-application when available but otherwise is not a requirement.

- 21) One comment objected that the proposed fall 2014 revision indicates “PCDs are not covered if there is any improvement after use of conservative therapy.” The concern is that “delaying implementation of therapeutic interventions in this manner does not represent sound clinical practice. Minimal improvement may not be clinically meaningful. Clinical interventions are made when the clinician determines that the patient, while perhaps exhibiting some incremental improvement, is not achieving the level of therapeutic goals that is appropriate in a given timeframe.”

Response: If there is improvement, it follows that the improvement may continue with current therapy. The logical end-point of conservative therapy may only be determined by serial re-examinations. If improvement fails to continue as documented by these serial re-examinations, then a PCD may be covered.

- 22) One comment objected that the proposed fall 2014 revision inappropriately “requires medications as part of conservative therapy.”

Response: The language has been changed to indicate medications should be used as clinically indicated.