

Medicare Part C Medical Coverage Policy

Pneumatic Compression Device

Origination: March 3, 2000 Review Date: April 19, 2023 Next Review: April 2025

***This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ***

DESCRIPTION OF PROCEDURE OR SERVICE

Pneumatic compression devices (PCD) consist of an inflatable garment for the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary between devices. Pneumatic devices are covered for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers.

Lymphedema is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. Lymphedema is manifested as primary or secondary and is caused by an interruption in the lymphatic drainage.

- Primary lymphedema is a relatively uncommon, chronic condition that 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
 radical surgical procedures with removal of regional groups of lymph nodes (for
 example, after radical mastectomy), post-radiation fibrosis, and spread of
 malignant tumors to regional lymph nodes with lymphatic obstruction, among other
 causes. It may also be a result from compression of the lymphatic and venous
 channels resulting from leakage of fluid into interstitial tissues in members with
 chronic venous insufficiency.

The goal of treatment for lymphedema is aimed at preventing further swelling or injury to the affected limb. First line treatment options should be instituted before progressing to pneumatic compression pumps. Multi-modal therapy is often more effective than single modality therapy.

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.

Peripheral Arterial Disease (PAD) is a circulatory problem in which narrowed arteries reduce blood flow to limbs, resulting in compromised blood flow to distal tissues and failure to keep up with oxygen demands.

POLICY STATEMENT

Coverage will be provided for lymphedema when it is determined to be medically necessary, as outlined in the below guidelines and medical criteria.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCD)s;
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE

Pneumatic compression devices (PCD) (E0650, E0651) are considered an appropriate treatment for refractory primary and secondary lymphedema, as well as Venous Stasis Ulcers:

Pneumatic compression pumps are only covered for purchase when the member has completed a successful trial. For the trial, the member must meet criteria: A (1 and 2) or B.

- A. A four (4) week trial rental will be covered for Primary and Secondary Lymphedema if:
 - 1. The member has undergone a four (4)-week attempt of conservative therapy that must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb;

And

2. The treating physician determines that there has been no significant improvement or significant symptoms remain after the conservative therapy;

OR

- B. A four (4) week trial rental will be covered for Venous Stasis Ulcers if:
 - 1. The member has edema of the affected lower extremity, one or more venous stasis ulcer(s) which have failed to heal after a six (6)-month trial of conservative therapy including a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.
- C. Once the trials are completed, purchase is covered if the additional criteria below are met:
 - 1. The four (4)-week rental trial of the pneumatic compression device was accomplished, **and**
 - 2. The patient can tolerate the device, and
 - **3.** In the provider's opinion there has been an appropriate clinical response, **and**
 - 4. The member can properly manage the device.
- D. Lymphedema Extending onto the Chest, Trunk and/or Abdomen; A PCD coded as E0652, is covered for the treatment of lymphedema extending onto the chest, trunk and/or abdomen when all the following are met:
 - 1. Member has lymphedema of an extremity as defined above
 - 2. The coverage criteria for E0650, E0651 are met
 - 3. The member has lymphedema extending onto the chest, trunk and/or abdomen that extends past the limits of a standard compression sleeve, and the chest, trunk and/or abdominal lymphedema has failed to improve with a four-week trial.
 - I. A four-week trial of conservative therapy demonstrating failed response to compliant treatment using E0650 or E0651 is required as well as all of the following:
 - a. Regular Exercise
 - b. Elevation where appropriate
 - c. Manual lymphatic drainage (where available) and selfmanual lymphatic drainage (MLD) for at least 30 minutes per day
 - d. Evaluation of diet and implementation of any necessary change

- e. Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.)
- f. Correction (where possible) of anemia and/or hypoproteinemia

WHEN COVERAGE WILL NOT BE APPROVED

- For indications other than cited above.
- When the medical guidelines shown above are not met.
- PCD E0675 used in the treatment of peripheral arterial disease is not reasonable and necessary and therefore not covered.
- In regard to lymphedema extending to the chest, trunk, and/or abdomen, at the end of the four-week trial, if there has been improvement of lymphedema extending onto the chest, trunk and/or abdomen, then reimbursement for an E0652 is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart. When and only when no significant improvement has occurred in the most recent four weeks and the coverage criteria above are still met, an E0652 is eligible for reimbursement.

LIMITATIONS

The use of pneumatic compression devices is contraindicated in those individuals with active infection, metastatic disease or radiation for lymphedema. Contraindications for CVI include serious arterial insufficiency, edema due to congestive heart failure, phlebitis, deep vein thrombosis, or a localized wound infection or cellulitis.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee reimbursement.

<u>Applicable codes</u>: E0650, E0651, E0652, E0655, E0656, E0657, E0660, E0665, E0666, E0667, E0668, E0669, E0670, E0671, E0672, E0673, A6545

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

Non-segmented Compression Devices

When a pneumatic compression device is covered, a **non-segmented device** (E0650) or segmented device without manual control of the pressure in each chamber (E0651) is generally sufficient to meet the clinical needs of the patient.

 A non-segmented compressor (E0650) with a segmented appliance/sleeve (E0671- E0673) is considered functionally equivalent to an E0651 compressor with a segmented appliance/sleeve (E0667-E0669).

Segmented Compression Devices

When a **segmented device** with manual control of the pressure in each chamber (E0652) is ordered and provided, payment will be based on the allowance for the least costly medically appropriate alternative, E0651, unless there is clear documentation of medical necessity in the individual case. (Examples may be significant skill scars or the presence of a contracture or pain caused by a clinical condition that requires more costly manual control.)

Full coverage for code E0652 will be approved only when there is documentation
that the individual has unique characteristics that prevent satisfactory pneumatic
compression treatment using a non-segmented device (E0650) with a
segmented appliance/sleeve (E0671-E0673) or a segmented device without
manual control of the pressure in each chamber (E0651).

References:

- Medicare National Coverage Determination for Pneumatic Compression Devices (280.6); Effective date: 1/14/2002: Accessed via http://www.cms.gov/3/21/2023.
- 2. Medicare Local Coverage Determination for Pneumatic Compression Devices CGS Administrators(L33829); Effective date: 10/01/2015, Revision Effective Date 12/1/2015; Accessed via http://www.cms.gov; 3/21/2023.

Policy Implementation/Update Information:

Revision Date: April 23, 2002; February 2004; June 9, 2004; June 28, 2006; February 20, 2008: Formatting and grammatical changes. No criteria changes made.

Revision Date: August 2012: changed policy title to from Lymphedema Pumps-Pneumatic Compression Devices to Pneumatic Compression Devices. Criteria added to differentiate between rental and purchase of the device.

Revision Date: August 20, 2014; Annual Review; Minor edits to mirror NCD and LCD.

Revision Date: December 16, 2015; updates to LCD L33829 – no major criteria changes, minor revisions to policy. Description of Procedure/Service – minor revision of definition to secondary lymphedema, added definition of Peripheral Artery Disease (PAD); Indication For Coverage – minor edit to item B1; When Coverage Will Not Be Approved – added reference to PCD E0675 used in treatment of PAD; Coding – added E0670 to policy.

Revision Date: December 20, 2017; Annual Review, No CMS Updates, Minor Revisions Only. Removed Reference #3 as it was retired

Revision Date: March 20, 2019; CMS Update. No Changes to Criteria were necessary. Minor Revisions Only.

Revision Date: February 17, 2021; Annual Review; No Changes to Criteria. Minor Revisions Only.

Revision Date: April 21, 2021; Staff Clarification; Addition: Indications for Coverage: Added codes for PCDs (E0650, E0651). Removal of When Coverage will Not be approved 'Appliances used for pneumatic compression of the chest or trunk (E0656 and E0657) will be denied as not medically necessary" As it isn't in the LCD any longer. Added: Indications for Coverage: D. Lymphedema Extending onto the Chest, Trunk and/or Abdomen; A PCD coded as E0652, is covered for the treatment of lymphedema extending onto the chest, trunk and/or abdomen when all the following are met:

Member has lymphedema of an extremity as defined above. The coverage criteria for E0650, E0651 are met. The member has lymphedema extending onto the chest, trunk and/or abdomen that extends past the limits of a standard compression sleeve, and the chest, trunk and/or abdominal lymphedema has failed to improve with a four-week trial. A four-week trial of conservative therapy demonstrating failed response to compliant treatment using E0650 or E0651 is required as well as all of the following: Regular Exercise, Elevation where appropriate, Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 30 minutes per day, Evaluation of diet and implementation of any necessary change, Medications as appropriate (e.g. diuretics and/or other treatment of congestive failure, etc.), Correction (where possible) of anemia and/or hypoproteinemia Also Added "When Coverage will not be Approved"; In regard to lymphedema extending to the chest, trunk, and/or abdomen, at the end of the four week trial, if there has been improvement of lymphedema extending onto the chest, trunk and/or abdomen, then reimbursement for an E0652 is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart. When and only when no significant improvement has occurred in the most recent four weeks and the coverage criteria above are still met, an E0652 is eligible for reimbursement. Revision Date: April 19, 2023; Annual Review. No CMS updates. Minor Revisions only.

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<u>Approval Dates:</u>
Medical Coverage Policy Committee: April 19, 2023

Policy Owner: Beth Sell, RN, BSN Medical Policy Coordinator