DME for Lymphedema Pumps/Garments

MPM 26.0

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Disclaimer

Refer to the member’s specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in these criteria.

Description

Item/Service Description

Pneumatic compression devices 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.

The term DME is defined as equipment which:

- Can withstand repeated use; i.e., could normally be rented, and used by successive patients;
- Is primarily and customarily used to serve a medical purpose;
- Generally, is not useful to a person in the absence of illness or injury; and
- Is appropriate for use in a patient’s home.
- Whether the item has been approved for marketing by the Food and Drug Administration (FDA) and is otherwise generally considered to be safe and effective for the purpose intended; and
- Whether the item is reasonable and necessary for the individual patient.

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

General Coverage Criteria

Pneumatic compression devices are covered only when prescribed by a physician’s (MD, DO, DPM) and Physician extenders (NP, PA, CNS) to the extent allowed by their applicable state scope-of-practice and
other license requirements; and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.

The determination by the physician of the medical necessity for a pneumatic compression device must be clearly documented to include:

- The patient's diagnosis and prognosis;
- Symptoms and objective findings, including measurements which establish the severity of the condition;
- The reason the device is required, including the treatments which have been tried and failed; and
- The clinical response to an initial treatment with the device.

I. LYMPHEDEMA:

PHP follows LCD (L33829) Pneumatic Compression Devices (PCD) and the related policy article LCA A52488. A PCD coded as E0650 or E0651 is covered for both primary and secondary lymphedema in members with chronic and severe lymphedema when ALL the following three requirements are met:

1. The member has a diagnosis of lymphedema as defined below, AND

2. The member has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings:
   - Marked hyperkeratosis with hyperplasia and hyperpigmentation
   - Papillomatosis cutis lymphostatica,
   - Deformity of elephantiasis,
   - Skin breakdown with persisting lymphorrhea,
   - Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology,

   AND

3. In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial (see below for trial guidelines)

A PCD coded as E0650 or E0651 used to treat edema from causes
other than lymphedema will be denied as not reasonable and necessary.

A PCD coded as E0652 is **not covered** for the treatment of lymphedema of the extremities alone even if the criteria in this section are met. Refer below to section III: LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN and PCD Code Selection for additional information about the limited coverage for PCD coded as E0652.

**Four-Week Trial for Lymphedema:**
A four-week trial of conservative therapy should be documented. It is required to document the response has failed to treatment. The four-week trial of conservative therapy must include all of the following in your documentation:

- Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
  - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point
  - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
- Regular exercise
- Elevation of the limb

When available, manual lymphatic drainage is a key component of conservative treatment as is appropriate medication treatment when there is concurrent congestive failure.

At the end of the four-week trial, if there has been improvement, then reimbursement for a PCD 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. Only when no significant improvement has occurred in the most recent four weeks and the coverage criteria above are still met, may the lymphedema be considered unresponsive to conservative therapy, and coverage for a PCD considered.

The determination of medical necessity by the physician for pneumatic compression device must include documentation for the following: diagnosis and prognosis; symptoms and objective findings to include measurements in which the severity of the
condition was established; reason the device is needed; provide information on treatments that were tried and failed; and the clinical response to an initial treatment with the device.

Re-assessments conducted for a trial must include detailed measurements, obtained in the same manner and with reference to the same anatomic landmarks, prior to and at the conclusion of the various trials and therapy, with bilateral comparisons where appropriate.

The trial of conservative therapy must be clearly documented in the member’s medical record before prescribing any type of pneumatic compression device (E0650-E0652). This assessment may be performed by the prescribing physician or any other licensed/certified medical professional (LCMP) who is directly involved in the care of lymphedema treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the prescribing physician must receive and review the report of the evaluation. In addition, the prescribing physician must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.

II. CHRONIC VENOUS INSUFFICIENCY (CVI) WITH VENOUS STASIS ULCERS

A PCD coded as E0650 or E0651 is covered for the treatment of CVI of the lower extremities only if the patient has ALL the following:

- Edema in the affected lower extremity
- One or more venous stasis ulcer(s)
- The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating physician. (See below for trial guidelines)

A PCD coded as E0650 or E0651 used to treat ulcers in locations other than the lower extremity or ulcers and wounds from other causes is not eligible and will be denied as not reasonable and necessary.

A PCD coded as E0652 is not covered for the treatment of CVI even if the criteria in this section are met. Claims will be denied as not reasonable and necessary. Refer below to the sections III Lymphedema Extending onto the Chest, Trunk and/or Abdomen.
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Six-Month Trial for CVI:
Documentation of the six-month trial of conservative therapy is required and must include the members response to failed treatment. The six-month trial of conservative therapy must include **ALL** of the following in your documentation:

- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
  - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point
  - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
- Medications as appropriate (e.g. diuretics and/or other treatment of congestive failure, etc.)
- Regular exercise
- Elevation of the limb
- Appropriate wound care for the ulcer (including sharp debridement where appropriate)

**At the end of the six-month trial**, if there has been improvement, then reimbursement for a PCD is not reasonable and necessary. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessments. When no significant improvement has occurred for a continuous period of six months and the coverage criteria above are still met, then the use of a PCD to treat CVI is eligible for reimbursement.

The trial of conservative therapy must be clearly documented in the member’s medical record before prescribing any type of pneumatic compression device (**E0650-E0652**). This assessment may be performed by the prescribing LCMP directly involved in the member’s CVI treatment. If the assessment is performed by an LCMP, the prescribing physician must receive and review the report of the evaluation. In addition, the prescribing physician must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.
III. LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN

A segmented, calibrated gradient pneumatic compression device (HCPCS code E0652) is only covered when the individual has unique characteristics which prevent them from receiving adequate satisfactory pneumatic compression treatment using a nonsegmented device along with a segmented appliance or compression device without manual control of the pressure in each chamber. A PCD coded as E0652, is covered for the treatment of lymphedema extending onto the chest, trunk and/or abdomen when ALL of the following are met:

• The beneficiary has lymphedema of an extremity as defined below
• The coverage criteria for an E0650 or E0651 are met
• The beneficiary 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. (See below for trial guidelines)

A PCD coded as E0652 used to treat lymphedema not extending onto the chest, trunk and/or abdomen or CVI is not eligible and will be denied as not reasonable and necessary.

Four-Week Trial for Lymphedema Extending onto the Chest, Trunk and/or Abdomen

A four-week trial of conservative therapy should be documented. It is required to document the response has failed to treatment with E0650 or E0651. The four-week trial of conservative therapy must include ALL of the following in your documentation.

• At least four weeks of regular, daily, multiple-hour home usage of the E0650 or E0651 after careful, in-person fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided
• Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
  o Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point
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- The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
  - 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

At the end of the four-week trial, if there has been improvement of the 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.

The trial of conservative therapy must be clearly documented in the beneficiary’s medical record before prescribing any type of pneumatic compression device (E0650-E0652). This assessment may be performed by the prescribing physician or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary’s lymphedema treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the prescribing physician must receive and review the report of the evaluation. In addition, the prescribing physician must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.

Exclusion/Limited Coverage

Peripheral Artery Disease (PAD)

PCD coded as E0675 to treat PAD is not eligible for reimbursement. There is insufficient evidence to demonstrate that reimbursement is justified. Claims for E0675 will be denied as not reasonable and necessary. Refer to LCD L33829 and related Policy Article (A52488) for nonmedical necessity coverage.

Deep Venous Thrombosis Prevention:

A PCD that provides intermittent limb compression for the purpose of prevention of venous thromboembolism (E0676) is a preventive service. Items that are used for a preventative service or function are
excluded from coverage under the Medicare DME benefit. Refer to LCD L33829 and related Policy Article (A52488) for nonmedical necessity coverage.

**Additional Limitation:**
A Pneumatic Compression Device (PCD) coded as E0652 has limited coverage. The NCD for Pneumatic Compression Devices (IOM 100-03, §280.6) provides:

"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."

The only “unique characteristics” identified in the clinical literature that requires the use of an E0652 device is lymphedema extending onto the chest, trunk and/or abdomen which has remained unresponsive to all other therapies.

**Definition**

**Edema:**
Edema is a non-specific term for the accumulation of fluid in tissue, most often in the extremities. There are numerous causes for edema, ranging from systemic disorders (e.g. congestive heart failure, etc.) to local conditions (post-surgery, congenital abnormalities, etc.). (Examples are not all-inclusive).

Lymphedema, as discussed below, is just one group of conditions that can be a cause of accumulation of fluid in the tissue. Lymphedema arises from disorders of the lymphatic system. It is essential to rule out other causes of edema in order to diagnose lymphedema. Edema from other causes is not classified as lymphedema for purposes of reimbursement for PCDs (E0650-E0652).

**Primary Lymphedema:**
Primary lymphedema is a disorder of the lymphatic system that occurs on its own. It is inherited and uncommon. Examples (not all-inclusive) are:

- Congenital lymphedema due to lymphatic aplasia or hypoplasia
- Milroy's disease, an autosomal dominant familial form of congenital lymphedema
- Lymphedema praecox
- Lymphedema tarda
Secondary Lymphedema:
Secondary lymphedema is a disorder of lymphatic flow that is caused by some other disease or condition. It is more common than primary lymphedema. It is most commonly caused by surgery (especially lymph node dissection, such as for breast cancer), radiation therapy (especially axillary or inguinal), trauma, lymphatic obstruction by tumor, and, in developing countries, lymphatic filariasis. Secondary lymphedema may also result from compression of the lymphatic and venous channels resulting from leakage of fluid into interstitial tissues in patients with chronic venous insufficiency. (See below)

Chronic Venous Insufficiency (CVI)

Lymphedema may also be caused by CVI when fluid leaks into the tissues from the venous system. 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. The incidence of lymphedema from CVI is not well established.

Peripheral Arterial Disease (PAD)

Peripheral artery disease is a circulatory problem in which narrowed arteries reduce blood flow to limbs, resulting in compromised blood flow to the distal tissue and failure to keep up with oxygen demands.

Prescriptions requirement:
Prescriptions for Pneumatic Compression Devices (PCDs) (E0650-E0652, E0675, E0676) are limited to Physicians (MD, DO, DPM) and physician extenders (NP, PA, CNS) to the extent allowed by their applicable state scope-of-practice and other license requirements. Providers must use care because the treatment of lymphedema, chronic venous insufficiency with ulceration and complications related to the treatment of these conditions by use of PCDs, commonly require consideration of diagnoses and management of systemic conditions. In no event should a provider order PCDs or PCD appliances that are to be used for or are to be applied to areas of the body that fall outside of their state scope of practice and other license limitations.

Coding
The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

ACCESSORIES CODING INSTRUCTIONS: See the Accessories section of the LCD (L33829) for the PCD related accessories for eligible coverage information.
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#### DME HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0650</td>
<td>Pneumatic compressor, non-segmental home model</td>
</tr>
<tr>
<td>E0651</td>
<td>Pneumatic compressor, segmental home model without calibrated gradient pressure</td>
</tr>
<tr>
<td>E0652</td>
<td>Pneumatic compressor, segmental home model with calibrated gradient pressure</td>
</tr>
<tr>
<td>E0655</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, half arm</td>
</tr>
<tr>
<td>E0656</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, trunk</td>
</tr>
<tr>
<td>E0657</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, chest</td>
</tr>
<tr>
<td>E0660</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, full leg</td>
</tr>
<tr>
<td>E0665</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, full arm</td>
</tr>
<tr>
<td>E0666</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, half leg</td>
</tr>
<tr>
<td>E0667</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, full leg</td>
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<tr>
<td>E0668</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, full arm</td>
</tr>
<tr>
<td>E0669</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, half leg</td>
</tr>
<tr>
<td>E0670</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk</td>
</tr>
<tr>
<td>E0671</td>
<td>Segmental gradient pressure pneumatic appliance, full leg</td>
</tr>
<tr>
<td>E0672</td>
<td>Segmental gradient pressure pneumatic appliance, full arm</td>
</tr>
<tr>
<td>E0673</td>
<td>Segmental gradient pressure pneumatic appliance, half leg</td>
</tr>
<tr>
<td>E0675</td>
<td>Pneumatic compression device, high pressure, rapid inflation/deflation cycle, arterial insufficiency (unilateral or bilateral system). Not covered for PAD, see exclusion section</td>
</tr>
<tr>
<td>E0676</td>
<td>Intermittent limb compression device (includes all accessories), not otherwise specified. Not-covered see exclusion section.</td>
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</table>

#### ICD-10 Diagnosis Codes

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<tr>
<th>ICD-10</th>
<th>ICD-10 Codes covered if selection criteria are met</th>
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</thead>
<tbody>
<tr>
<td>I89.0</td>
<td>Lymphedema, not elsewhere classified</td>
</tr>
<tr>
<td>I89.1</td>
<td>Lymphangitis</td>
</tr>
<tr>
<td>I89.8</td>
<td>Other specified noninfective disorders of lymphatic vessels and lymph nodes</td>
</tr>
<tr>
<td>I89.9</td>
<td>Noninfective disorder of lymphatic vessels and lymph nodes, unspecified</td>
</tr>
<tr>
<td>I97.2</td>
<td>Postmastectomy lymphedema syndrome [vascularized lymph node transfer not covered for the treatment of post-hyphenmastectomy lymphedema or for the treatment of</td>
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<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Codes covered if selection criteria are met</th>
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</thead>
<tbody>
<tr>
<td>Q82.0</td>
<td>Hereditary lymphedema</td>
</tr>
</tbody>
</table>

**References**

1. CMS, LCD- L33829, Pneumatic Compression Devices, Revision Number 9, Revision Date 01/01/2019. Related Article (A52488), Revision date 01/01/2017, R#7. Accessed 12/18/2019.


**Approval Signatures**

Clinical Quality/Utilization. Mgmt. Committee: Howard Epstein MD

Medical Directory: Norman White MD

**Approval Dates**

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**Publications History**

09-26-18 Policy effective date 09/26/2018.

01-22-20 Annual review. No content change. Update web links. Removed codes S8420 - S8428, S8950 and A6530 – A6549. These codes are not applicable to this policy.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines,
additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: Click here for Medical Policies