

Medical Policy



Pneumatic Compression Pumps (Segmental and Non-segmental)

Policy Guidelines

Coverage Criteria:

1. Must be ordered by the Member's treating physician.
2. **Lymphedema** is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. The accumulation of lymph fluid results from impairment to the normal clearing function of the lymphatic system and/or from an excessive production of lymph. Lymphedema is divided into two broad classes according to etiology.

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.

GENERAL

PCDs coded as E0650-E0652 are used only in the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers. Reimbursement for these items is based upon the criteria in the following sections. PCD coded as E0675 is used in the treatment of peripheral arterial disease. Claims for E0675 will be denied as not reasonable and necessary as outlined below.

I - LYMPHEDEMA

A PCD coded as E0650 or E0651 is covered for both primary and secondary lymphedema in beneficiaries with chronic and severe lymphedema when all of the following three requirements are met:

1. The beneficiary has a diagnosis of lymphedema as defined above, and
2. The beneficiary 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 lymphedema that does not meet all of the requirements above is not considered reasonable and necessary.

A PCD coded as E0650 or E0651 used to treat edema from causes other than lymphedema is not considered 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 and considered not reasonable and necessary. Refer below to the sections 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 demonstrating failed response to treatment is required. The four-week trial of conservative therapy must include all of the following:

- 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 further 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.

CMS' NCD for PCD (280.6) instructs: "The determination by the physician of the medical necessity of a pneumatic compression device must include...symptoms and objective findings, including measurements which establish the severity of the condition."

At a minimum, 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.

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

A PCD coded as E0650 or E0651 is covered for the treatment of CVI of the lower extremities only if the patient has all of 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 CVI that does not meet all of the requirements above is not considered reasonable and necessary.

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 considered 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 considered not reasonable and necessary. Refer below to the sections 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.

Six-Month Trial for CVI

A six-month trial of conservative therapy demonstrating failed response to treatment is required. The six-month trial of conservative therapy must include all of the following:

- 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 further 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 documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650-E0652

III - LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN

The CMS National Coverage Decision for Pneumatic Compression Devices (280.6) instructs:

“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 non-segmented device in conjunction with a segmented appliance or a segmented compression device without manual control of 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:

1. The member has lymphedema of an extremity as defined above
2. The coverage criteria for an E0650 or 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. (See below for trial guidelines)

A PCD coded as E0652 used to treat lymphedema extending onto the chest, trunk and/or abdomen that does not meet all of the requirements above is considered not reasonable and necessary.

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

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

A four-week trial of conservative therapy demonstrating failed response to treatment with and E0650 or E0651 is required. The four-week trial of conservative therapy must include all of the following:

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
 - 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 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 any 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 further 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 documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650-E0652).

IV – PERIPHERAL ARTERY DISEASE (PAD)

A PCD coded as E0675 to treat PAD is not considered reasonable and necessary. There is insufficient evidence to demonstrate justification.

V – DEEP VENOUS THROMBOSIS PREVENTION

A PCD coded as E0676 is used only for prevention of venous thrombosis. Devices used for prophylaxis of venous thrombosis are considered not reasonable and necessary.

ACCESSORIES

PCD related accessories (E0655-E0673) are eligible for reimbursement only when the appropriate, related base PCDs (E0650-E0651, E0675) meets the applicable coverage criteria for that type of PCD. If the base PCD is not covered, related accessories are not covered.

HCCS Level II Codes and Description

E0650 PNEUMATIC COMPRESSOR, NON-SEGMENTAL HOME MODEL

E0651 PNEUMATIC COMPRESSOR, SEGMENTAL HOME MODEL WITHOUT CALIBRATED GRADIENT PRESSURE

E0652 PNEUMATIC COMPRESSOR, SEGMENTAL HOME MODEL WITH CALIBRATED GRADIENT PRESSURE

E0655 NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, HALF ARM

E0656 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, TRUNK

E0657 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, CHEST

E0660 NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL LEG

E0665 NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL ARM

E0666 NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, HALF LEG

E0667 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL LEG

E0668 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL ARM

E0669 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, HALF LEG

E0670 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC

COMPRESSOR, INTEGRATED 2 FULL LEGS AND TRUNK

E0671 SEGMENTAL GRADIENT PRESSURE PNEUMATIC APPLIANCE, FULL LEG

E0672 SEGMENTAL GRADIENT PRESSURE PNEUMATIC APPLIANCE, FULL ARM

E0673 SEGMENTAL GRADIENT PRESSURE PNEUMATIC APPLIANCE, HALF LEG

Documentation Requirements:

Items in this policy may be subject to the Affordable Care Act (ACA) 6407.

The Affordable Care Act (ACA) 6407 requires that the treating physician conduct a face-to-face examination during the six month period preceding the written order. The documentation must be received by the provider prior to delivery for certain DME items. The documentation must describe a medical condition for which the DME is being prescribed.

▼ Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood’s policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

▼ **References**

Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents; December 2015. Accessed December 18, 2017.

CGS Administrators, LLC. Jurisdiction B DME MAC, Pneumatic Compression Devices. Local Coverage Determination No. L33829; revised date December 1, 2015. Reviewed December 2018.

Noridian Healthcare Solutions, LLC. Pneumatic Compression Devices. Local Coverage Determination No. L33829 Durable Medical Equipment Medicare Administrative Carrier Jurisdiction A; revised February 4, 2011. Reviewed December 2018.

Applicable URAC Standard

Core 8	Staff operational tools and support
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Change/Authorization History

Revision Number	Date	Description of Change	Prepared/Reviewed by	Approved by	Review Date:
A	Nov.2006	Initial Release	Rosanne Brugnoni	Ken Fasse	n/a
01	Jan.2007	Revised documentation requirements	Susan Glomb	Ken Fasse	
02		Annual Review / no revisions	Susan Glomb	Ken Fasse	Dec.2008
03	01-01-09	Added denial statement regarding appliances for the chest and trunk. Added:E0656 and E0657	Susan Glomb	Ken Fasse	
04		Annual Review/ no changes	Susan Glomb	Ken Fasse	12-22-09
05		Annual Review – No changes	Susan Glomb	Ken Fasse	12-03-10

06	01-07-11	Deleted: Least costly alternative language for E0652	Susan Glomb	Ken Fasse	
07	11-10-11	Annual Review. Added References to Policy	Susan Glomb	Dr. B. Almasri	Nov. 2011
08	11-29-12	Annual review – no changes.	Susan Glomb	Dr. B. Almasri	Nov. 2012
09	12-30-13	Annual review. Added Code E0670, Segmental Pneumatic Appliance for use with pneumatic compressor, integrated, 2 full legs and trunk. Appliances used for pneumatic compression of the chest or trunk E0656m E0657 E0670 will be considered not reasonable and necessary.	Susan Glomb	Dr. B. Almasri	
10	12-3-14	Annual Review. Added: Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements.	Susan Glomb	Dr. B. Almasri	
11	12-8-15	Annual Review. Added info re: update to E0652. References updated.	Susan Glomb	Dr. B. Almasri	
12	12-14-16	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	December 2016
13	12-18-17	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2017
14	12-7-18	Annual review. Updated Medicare references.	Carol Dimech	Dr. C. Lerchin	December 2018