

Pneumatic Compression Devices

L33829

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Contractor Information

LCD Information

Document Information

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L33829

LCD Title

Pneumatic Compression Devices

Proposed LCD in Comment Period

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CMS National Coverage Policy

CMS Pub. 100-03, (Medicare National Coverage Determinations Manual), Chapter 1, Section 280.6

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

PRESCRIPTIONS

Prescriptions for Pneumatic Compression Devices (PCDs) (E0650, E0651, 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.

DEFINITIONS

For Medicare DMEPOS reimbursement purposes the following definitions are used in this policy.

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 Medicare reimbursement for PCDs (E0650, E0651, 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.

GENERAL

PCDs coded as E0650, E0651, 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 eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0650 or E0651 used to treat edema from causes other than lymphedema is not eligible for reimbursement. Claims 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. Claims will be denied as 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 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 medical necessity determination for a PCD by the treating practitioner must include symptoms and objective findings, including measurements, to establish the severity of the condition.

The documentation by the treating practitioner of the medical necessity of a pneumatic compression device must 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

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.

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650, E0651, E0652). This assessment may be performed by the treating practitioner 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 treating practitioner must receive and review the report of the evaluation. In addition, the treating practitioner 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 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 practitioner. (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 eligible for reimbursement. Claims will be denied as not 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 eligible for reimbursement. Claims 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 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 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 documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650, E0651, E0652). This assessment may be performed by the treating practitioner or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's CVI 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 treating practitioner must receive and review the report of the evaluation. In addition, the treating practitioner 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 above
- 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 extending onto the chest, trunk and/or abdomen that does not meet all of the requirements above is not eligible for reimbursement. Claims will be denied as 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 eligible for reimbursement. Claims 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 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 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 documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650, E0651, E0652). This assessment may be performed by the treating practitioner 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 treating practitioner must receive and review the report of the evaluation. In addition, the treating practitioner 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.

IV – PERIPHERAL ARTERY DISEASE (PAD)

A 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.

V – DEEP VENOUS THROMBOSIS PREVENTION

A PCD coded as E0676 is used only for prevention of venous thrombosis. Refer to the related Policy Article NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about lack of a Medicare benefit for devices used for prophylaxis of venous thrombosis.

ACCESSORIES

PCD related accessories (E0655, E0656, E0657, E0660, E0665, E0666, E0667, E0668, E0669,

E0670, E0671, E0672, E0673) are eligible for reimbursement only when the appropriate, related base PCDs (E0650, E0651, E0652, E0675) meets the applicable coverage criteria for that type of PCD. If the base PCD is not covered, related accessories are not eligible for reimbursement. Claims for related items will be denied as not reasonable and necessary.
PCD CODE SELECTION (E0650, E0651, E0652, E0675, E0676)

A PCD coded as E0650 or E0651 is used for lymphedema or CVI. An E0650 compressor with a segmented appliance/sleeve (E0671, E0672, E0673) is considered functionally equivalent to an E0651 compressor with a segmented appliance/sleeve (E0667, E0668, E0669).

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.

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.

A PCD coded as E0675 is used only for peripheral artery disease. Other PCD codes are not used for this condition.

A PCD coded as E0676 is used only for prevention of venous thrombosis. Refer to the related Policy Article NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about lack of a Medicare benefit for devices used for prophylaxis of venous thrombosis.

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

Summary of Evidence

NA

Analysis of Evidence (Rationale for Determination)

NA

Coding Information

CPT/HCPCS Codes

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Group 1

(18 Codes)

Group 1 Paragraph The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIER:

EY - No physician or other health care provider order for this item or service.

HCPCS CODES: Group 1 Codes

Code	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
E0675	PNEUMATIC COMPRESSION DEVICE, HIGH PRESSURE, RAPID INFLATION/DEFLATION CYCLE, FOR ARTERIAL INSUFFICIENCY (UNILATERAL OR BILATERAL SYSTEM)
E0676	INTERMITTENT LIMB COMPRESSION DEVICE (INCLUDES ALL ACCESSORIES), NOT OTHERWISE SPECIFIED

General Information

Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider". It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

Miscellaneous

Appendices

Utilization Guidelines

Refer to Coverage Indications, Limitations and/or Medical Necessity

Sources of Information

N/A

Bibliography

NA

Related Local Coverage Documents

Articles

[A52488 - Pneumatic Compression Devices - Policy Article](#)

[A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#)

Related National Coverage Documents

N/A