

Pneumatic Compression Devices

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification as applicable.

Pneumatic compression devices require precertification and physician face-to-face.

It must be within a practitioner’s scope of practice to manage systemic intravascular changes and fluid shifts caused by pneumatic compression devices to order the devices.

National Coverage Determination Policy	CMS Publication 100-3 Medicare National Coverage Determinations Manual, Chapter 1, Section 280.6
Local Coverage Determination Policy	J-B/C
Effective Date	For service performed on or after 10/31/13
Revision/Review Date	01/19, 10/18, 06/06/18, 07/01/17, 07/01/16, 09/15/14
The Health Plan	Plans will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreements, or benefit plan documents.

DESCRIPTION

A pneumatic compression pump is a medical device consisting of sequential air chambers that produce a graded pressure on a limb via a proximally moving pressure wave. It is used to promote peripheral circulation, and to treat various medical conditions, such as lymphedema, leg ulcers, and lymphostatic disorders.

COVERAGE GUIDELINES

Pneumatic compression devices are covered for the treatment of primary or secondary lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers. If the coverage criteria below is not met the devices will be denied as not reasonable and necessary.

LYMPHEDEMA

Pneumatic compression devices (E0650, E0651) are covered in the home setting for the treatment of lymphedema if the member has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. *See Documentation Requirements section.*

The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, appropriate wound dressings, and elevation of the limb. There must be documentation of member compliance with these regimes. The garment may be prefabricated or custom-fabricated, but must provide adequate graduated compression. *See below for further coverage guidelines.*

CHRONIC VENOUS INSUFFICIENCY WITH VENOUS STASIS ULCERS

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. *See Documentation Requirements section.*

Pneumatic compression devices (E0650, E0651) are covered in the home setting for the treatment of CVI of the lower extremities only if the member has one or more venous stasis ulcer(s) with edema, which have failed to heal after a six month trial of conservative therapy, as indicated above.

PNEUMATIC COMPRESSION FOR CHEST TRUNK ABDOMEN

E0652 with chest or trunk sleeves (E0656, E0657, E0670) used with appropriate extremity sleeves are covered in cases of primary or secondary lymphedema and the lymphedema has failed to improve after four weeks of documented specific conservative therapy of all the above:

1. manual lymphatic drainage, and
2. exercise, and
3. dietary changes, and
4. diuresis, and
5. review and treatment of anemia, hyponatremia, etc. if indicated, and
6. compression garment of extremities, and then a
7. four week trial with daily use of a pneumatic compression device, E0650 or E0651.

The information submitted must indicate cause of lymphedema, history, and detailed description of severity, including ongoing measurements of all affected areas taken during the trial period. The submitted information must also include the member's compliance with treatment and an overview of the technician/physician interventions.

In cases of use for chest, trunk, and abdomen lymphedema, if authorized, the authorization for the compression device will be on a rental basis. This includes both the device and any appliances used with the device.

A segmented device with manual control pressure in each chamber (E0652) provided for use limited to the extremities will be denied.

PERIPHERAL VASCULAR DISEASE

The Health Plan considers the pneumatic compression device, code **E0675**, as an alternative to vascular surgery for members with a diagnosis of peripheral artery disease where surgical intervention is indicated, but medically contraindicated d/t one or more factors. In these cases the device can only be ordered by the treating vascular surgeon. The angiography and the surgeons' treatment note that explains the severity of the peripheral vascular disease, the need for surgery, and the contraindications must be submitted with precertification.

Because an arterial pneumatic compression device (**E0675**) is covered only as an alternative to indicated vascular surgery when such surgery cannot be performed for reasons of medical contraindications, prescriptions for arterial PCD are limited to vascular surgeons (i.e., surgeons who regularly perform the indicated vascular surgery but cannot for this patient given the documented medical contraindications).

If the device is authorized, the authorization will be for three months only. To extend authorization the member is required to have a 60 - 90 day follow-up with the treating/ordering vascular surgeon and documentation must be submitted to The Health Plan showing that the member is benefitting from use of the device.

FOOT/HAND SEGMENTS

When a foot or hand segment is used in conjunction with a leg or arm appliance, respectively for any of the above devices, there should be no separate billing for this segment. Sleeves E0667-E0669 are used with E0675. It is considered included in the code for the leg or arm appliance.

See MEDICARE DEFINITIONS AND DESCRIPTION below for what comprises a 4 and 6 week trial.

NONCOVERAGE STATEMENT

The Health Plan does not cover pneumatic compression devices of the genitals. There is a lack of peer-reviewed published literature evaluating the clinical utility of compression garments for these anatomical sites.

E0650/E0651 are not covered for the treatment of edema not caused by lymphedema.

The use of a compression device for the treatment of ulcers other than the lower extremity and wounds from causes other than Chronic Venous Insufficiency is not covered.

E0652 is not covered for the treatment of Chronic Venous Insufficiency regardless of other guidelines met.

E0652 is not covered for the treatment of lymphedema of the extremities alone even if the criteria in this section are met.

The Health Plan considers use of **E0675** experimental and investigational for the treatment of peripheral artery disease without the need for surgery, arterial insufficiency, and for all other indications because the effectiveness for these indications has not been established.

Other types of PCD referred to as deep vein thrombosis (DVT) pumps, massage therapy pumps, post-surgical DVT preventative pumps, etc. (not all inclusive) are coded:

E0676 - INTERMITTENT LIMB COMPRESSION DEVICE (INCLUDES ALL ACCESSORIES), NOT OTHERWISE SPECIFIED

Code **E0676** will not be covered as a treatment option for lymphedema in the home setting, as there are more appropriate codes/devices to use for pneumatic compression devices.

Code **E0676** is not covered for use in prevention of illness or disease, i.e., post-operative prevention of DVT. It is statutorily excluded from coverage per Medicare. For these situations The Health Plan is adopting Medicare’s policy across all product lines.

The garments/sleeves that are used with **E0676** are included in the payment for **E0676** on initial issue and must not be billed separately.

A provider who bills separately for the garment/sleeve at the time of initial issue should use HCPCS code **A9900 - MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE**. It will be noted as not separately payable on the referral or claim.

HCPCS code **A4600 - SLEEVE FOR INTERMITTENT LIMB COMPRESSION DEVICE, REPLACEMENT ONLY, EACH** is used only when the sleeve is being replaced, not at the time of initial issue. This code may only be used with compressors coded with E0676. Code A4600 will be denied as non-covered as the compressor E0676 is not covered.

HCPCS codes **E0655 – E0673** must not be used when billing for garments used with E0676 devices.

cgsmedicare.com/jc/coverage/PDFs/A51306.pdf

<http://ngsmedicare.com>

REPAIR, REPLACEMENT AND REASONABLE USEFUL LIFETIME

Replacements and repairs require precertification. See **Replacement and Repair** policy.

Repairs are not separately payable during rental period.

Replacements are not covered due to neglect or misuse.

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS

EY	NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE
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GA	WAIVER OF LIABILITY STATEMENT ISSUED AS REQUIRED BY PAYOR POLICY, INDIVIDUAL CASE.
GZ	ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY
KX	REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET

HCPCS CODES

A4600	SLEEVE FOR INTERMITTENT LIMB COMPRESSION DEVICE, REPLACEMENT ONLY, EA
A9900	MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR COMPONENT OF ANOTHER HCPCS CODE
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)

There are no specific diagnoses or ICD-10 codes that indicate medical necessity

DOCUMENTATION REQUIREMENTS

For any of the above indications, pneumatic compression devices are covered only when prescribed by a physician, and when they are used with appropriate physician oversight, i.e., physician evaluation of the member'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.

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician'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 with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
 - a. Member's name
 - b. Date
 - c. Description of item. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required
 - d. Order must include diagnosis code
 - e. Physician signature with date. Date stamps are not appropriate
 - f. Quantity of items required and duration: A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used

The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that item. This information must be available upon request usually with precertification per Health Plan policy.

For pneumatic compression devices, the documentation would indicate the following for lymphedema:

- a. Member's prognosis;
- b. Symptoms and objective findings, including detailed measurements over time which establishes the severity of the condition;
- c. Reason the device is required, including the treatments which have been tried and failed; i.e., the conservative treatment, and
- d. Clinical response to an initial treatment with the device. (first 30 - 60 day trial period).

The clinical response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the member (or caregiver) to apply the device for continued use in the home.

For chronic venous insufficiency with venous stasis ulcers, documentation addressing all of the following must be submitted with precertification:

- a. The location of venous stasis ulcer(s), and
 - b. How long each ulcer has been continuously present, and
 - c. Previous treatment with a compression bandage system or compression garment,
 - d. Appropriate dressings for the ulcer(s), exercise, and limb elevation for at least the past six months, and
 - e. Evidence of regular physician visits for treatment of venous stasis ulcer(s) during the past six months.
3. Proof of delivery to be kept on file by the provider of the item.

Note: If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

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 member. 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).

If E0652 is requested, the following additional documentation is required:

1. The pressure in each chamber, and the frequency and duration of each treatment episode, and
2. Whether a segmented compressor without calibrated gradient pressure (E0651) or a non-segmented compressor (E0650) with a segmented appliance (E0671-E0673) had been tried and the results, and

3. The name, model number, and manufacturer of the device
4. Why the features of the device that was provided are needed, and
5. Clear documentation of the unique characteristics present that prevent appropriate pneumatic compression using a non-segmented device (E0650) with a segmented appliance/sleeve (E06071-E0673) or a segmented device without manual control of the pressure in each chamber (E0651).

PNEUMATIC COMPRESSION PROVIDED IN A PART A COVERED FACILITY

Reimbursement for pneumatic compression devices provided to a member while the member is covered in a Part A facility (hospital, inpatient acute rehabilitation, or long-term acute care facility) will be included in the facility reimbursement, if the device is intended for use while the member is in the facility for inpatient treatment or rehabilitation. A claim must not be submitted in this situation. In order for it to be billed separately, it must be given two days or less before discharge from a Part A covered stay, it must meet the above guidelines and be medically necessary for home use.

Reimbursement for a compression device while a member is in a skilled nursing facility (SNF) receiving Part A services, will be reimbursed according to individual facility contracts. In order for it to be billed separately, it must be given two days or less before discharge from a Part A covered stay; it must meet the above guidelines and be medically necessary for home use.

EQUIPMENT RETAINED FROM A PRIOR PAYOR:

The Health Plan will not pay in excess of the contracted purchase price for any item in this policy. If the provider is seeking payment from The Health Plan, the item must be precerted and The Health Plan will pay the remaining rental months up to purchase price- if member meets guidelines above.

BILLING GUIDELINES

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.

A non-segmented pneumatic compressor (E0650) is a device, which has a single outflow port on the compressor. The fact that the air from the single tube may be transmitted to a sleeve/appliance with multiple compartments or segments (E0671 - E0673) does not affect the coding of the compressor.

A segmented pneumatic compressor (E0651, E0652) is a device, which has multiple outflow ports on the compressor which lead to distinct segments on the appliance which inflate sequentially. A segmented device without calibrated gradient pressure (E0651) is one in which either (a) the same pressure is present in each segment or (b) there is a predetermined pressure gradient in successive segments, but no ability to individually set or adjust pressures in each of several segments. In an E0651 device the pressure is usually set by a single control on the distal segment. A segmented device with calibrated gradient pressure (E0652) is characterized by a manual control on at least three outflow ports, which can deliver an individually determined pressure to each segmental unit. The fact that the tubing and/or appliance are capable of achieving a pressure gradient does not classify the compressor as E0652 because this is not a calibrated gradient pressure.

Segmental gradient pressure pneumatic appliances (E0671 - E0673) are appliances/sleeves which are used with a non-segmented pneumatic compressor (E0650) but which achieve a pressure gradient through the design of the tubing and/or air chambers.

A non-segmented pneumatic compressor (E0650) is used with appliances/sleeves coded by E0655 - E0666 or E0671 - E0673. Segmented pneumatic compressors (E0651 or E0652) are used with appliances/sleeves coded by E0667 - E0669.

The only products that may be billed to The Health Plan using codes E0650, E0651, E0652, and E0675 are those for which a coding verification review has been made by the Pricing, Data Analysis, and Coding (PDAC) contractor and subsequently published on the appropriate Product Classification List.

Information concerning the documentation that must be submitted to the PDAC for a coding verification review can be found on the PDAC website or by contacting the PDAC.

Suppliers should contact the PDAC concerning the correct coding for these items.

KX, GA, and GZ MODIFIERS

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If the coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Suppliers should contact the PDAC contractor for guidance on the correct coding of these items. dmepdac.com/

MEDICARE DEFINITIONS AND DESCRIPTION

Lymphedema involves blockage of the lymph vessels, with a resulting accumulation of lymphatic fluid in the interstitial tissues of the body. When the vessels are damaged or missing, the lymph fluid cannot move freely throughout the system, but accumulates. This accumulation of fluid results in abnormal swelling of the arm(s) or leg(s), and occasionally swelling in other parts of the body.

Lymphedema is divided into two broad classes, they are primary lymphedema and secondary lymphedema. Primary lymphedema is a relatively uncommon, inherited, condition, which may occur in

members diagnosed with Milroy's Disease, lymphedema praecox, lymphatic aplasia, or lymphedema tarda.

Secondary lymphedema results from the destruction of, or damage to, formerly functioning lymphatic channels, by means of, but not limited to; radical surgical procedures (i.e., after radical mastectomy), post-radiation fibrosis, lymphatic obstruction due to the spread of malignant tumors to regional lymph nodes, and chronic venous insufficiency, among other causes.

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
 1. 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
 2. 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

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.
 1. 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.
 2. 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)

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MEDICARE CERTIFICATE OF MEDICAL NECESSITY:



DME CMN
Osteogenesis Stimu

INTERNET LINKS AND SOURCES

National Government Services website. Medical Policy Center. Durable Medical Equipment. Pneumatic Compression Devices. Local Coverage Determination LCD L27028 and Article A47127. Jurisdiction B. Last accessed 10/31/18. Retrieved from <http://ngsmedicare.com>

CGS Medicare: A Celerian Group Company. Local Coverage Determination Policy. Pneumatic Compression Devices. Jurisdiction C. LCD L5017. Article A24141. Last accessed 10/31/18. Retrieved from cgsmedicare.com/jc/coverage/lcdinfo.html

West Virginia Medicaid Internet Provider Manual. Chapter 506. Covered Services, Limitations, and Exclusions for DME Medical Supplies. Last accessed 10/31/18. Retrieved from dhhr.wv.gov/bms/Pages/default.aspx

Face-to-Face Examination and Prescription Requirements Prior to the Delivery of Certain DME Items Specified in the Affordable Care Act DME MAC Joint Publication. Posted February 20, 2014. Last accessed 10/31/18. Retrieved from www.cms.gov › ... › Medical Review and Education

The Pricing, Data Analysis, and Coding Contractor. Noridian. Internet website. Last accessed 10/31/18. Retrieved from <https://www.dmepdac.com/dmecsapp/>

Hayes Technology Brief. Flexitouch System (Tactile Systems Technology Inc.) for Lymphedema. Publication Date: 3/2017. Updated 11/12/18. Last accessed 01/01/19, Retrieved From: <https://www.hayesinc.com>

Hayes Technology Brief. Pneumatic Compression for Prevention of Deep Vein Thrombosis Following Total Knee Arthroplasty. Publication date. 11/20/18. Last Accessed 01/01/19. Retrieved From: <https://www.hayesinc.com>

The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11