

MEDICAL POLICY		Compression: Outpatient Pneumatic Devices (All Lines of Business Except Medicare)	
Effective Date: 05/01/2020		Section: DME	Policy No: 191
 <div style="text-align: right;">05/01/2020</div>		Technology Assessment Committee approved Date: 10/13; 9/14; 9/15 Medical Policy Committee approved Date: 7/09; 10/10; 12/11; 8/12; 2/13; 5/16; 7/17; 9/18; 11/19; 04/2020	
		Medical Officer	Date

See Policy HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayn Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Notes:

- In compliance with the Affordable Care Act and Women’s Health and Cancer Rights Act of 1998, the use of outpatient pneumatic compression devices following mastectomy are considered medically necessary.
- The following criteria are based on the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD): Pneumatic Compression Devices (L33829), Local Coverage Article (LCA): Pneumatic Compression Devices (A52488), National Coverage Determination (NCD): Pneumatic Compression Devices (280.6), and LCA: A55426, Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs.¹⁻⁴

Lymphedema *Not* Extending to the Chest, Trunk, and/or Abdomen

- I. A pneumatic compression device (PCD)(E0650, E0651) may be considered **medically necessary and covered** for both primary and secondary lymphedema in patients with chronic and severe lymphedema when **all** of the following (A.-C.) criteria are met:
 - A. The patient has a diagnosis of lymphedema (defined in Policy Guidelines section); **and**
 - B. The patient has persistence of chronic and severe lymphedema as identified by the documented presence of **at least one** of the following (1.-5.) clinical findings:
 1. Marked hyperkeratosis with hyperplasia and hyperpigmentation; **or**
 2. Papillomatosis cutis lymphostatica; **or**
 3. Deformity of elephantiasis; **or**
 4. Skin breakdown with persisting lymphorrhea; **or**
 5. Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology; **and**
 - C. In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required **4-week** trial. The 4-week trial of conservative therapy must include **all** of the following (1.-3.):
 1. Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression; **and**

Notes:

 - 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.
 2. Regular exercise; **and**
 3. Elevation of the limb.
- II. A PCD is considered **not medically necessary and is not covered** when criterion I. above is not met including, but not limited to, a PCD for the treatment of edema from causes other than lymphedema.

Lymphedema Extending to the Chest, Trunk, and/or Abdomen

Note: The CMS National Coverage Determination for Pneumatic Compression Devices (280.6) states, "(t)he 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."

III. A PCD with calibrated gradient pressure (E0652) may be considered **medically necessary and covered** for the treatment of lymphedema extending onto the chest, trunk, and/or abdomen when **all** of the following (A.-D.) criteria are met:

- A. The patient has lymphedema of an extremity (defined in Policy Guidelines section); **and**
- B. The patient meets criterion I. above; **and**
- C. The patient has lymphedema extending onto the chest, trunk, and/or abdomen that extends past the limits of a standard compression sleeve; **and**
- D. The chest, trunk, and/or abdominal lymphedema has failed to improve with a **4-week** trial of treatment with E0650 (pneumatic compression, non-segmental) **or** E0651 (pneumatic compressor, segmental, without calibrated gradient pressure). The 4-week trial of therapy must include **all** of the following (1.-8.):
 - 1. At least 4 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; **and**
 - 2. Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression; **and**

Notes:

- 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.
- 3. Regular exercise; **and**
- 4. Elevation where appropriate; **and**
- 5. Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 20 minutes per day; **and**
- 6. Evaluation of diet and implementation of any necessary change; **and**
- 7. Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.); **and**
- 8. Correction (where possible) of anemia and/or hypoproteinemia.

IV. A PCD with calibrated gradient pressure (E0652) is considered **not medically necessary and is not covered** when criterion III. above is not met including, but not limited to, the treatment of lymphedema not extending onto the chest, trunk, and/or abdomen or the treatment of chronic venous insufficiency.

Chronic Venous Insufficiency with Venous Stasis Ulcers

V. A pneumatic compression device (PCD)(E0650, E0651) may be considered **medically necessary and covered** for the treatment of chronic venous insufficiency (CVI) of the lower extremities when **all** of the following (A.-C.) criteria are met:

- A. Patient has edema in the affected lower extremity; **and**
- B. One or more venous stasis ulcer(s); **and**
- C. The ulcer(s) have failed to heal after a **6-month** trial of conservative therapy directed by the treating practitioner. The 6-month trial of conservative therapy must include **all** of the following (1.-5.):

- 1. Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression; **and**

Notes:

- 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.
- 2. Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.); **and**
 - 3. Regular exercise; **and**
 - 4. Elevation of the limb; **and**
 - 5. Appropriate wound care for the ulcer (including sharp debridement where appropriate)

- VI. A PCD is considered **not medically necessary and is not covered** when criterion III. above is not met including, but not limited to, the treatment of ulcers in locations other than the lower extremity or ulcers and wounds from other causes.

Peripheral Artery Disease

- VII. A pneumatic compression device for arterial insufficiency (E0675) is considered **not medically necessary and is not covered** for the treatment of peripheral artery disease.

Deep Venous Thrombosis Prevention

- VIII. Outpatient use of intermittent pneumatic compression devices for the prevention of deep venous thrombosis (DVT) may be considered **medically necessary and covered** when **all** of the following (A.-B.) criteria are met:

- A. The patient is unable to ambulate for a prolonged period of time (e.g., >2 weeks) due to trauma, orthopedic surgery, neurosurgery, or other acute circumstances; **and**
- B. The patient has a contraindication to standard short-term anticoagulation.

- IX. Outpatient use of intermittent pneumatic compression devices are considered **not medically necessary and are not covered** when criterion VIII. above is not met, including when the patient is able to walk or is no longer bedridden.

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Accessories

- X. Pneumatic compression device (PCD) related accessories (E0655-E0673) may be considered **medically necessary and covered** only when the appropriate, related base PCD (E0650, E0651, E0675) meets the applicable coverage criteria for that type of PCD.
- XI. PCD related accessories are considered **not medically necessary and are not covered** when criterion IX. above is not met.

POLICY GUIDELINES

Definitions

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-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)

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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.

Four-Week Conservative Therapy Trial for Lymphedema Not Extending Onto the Chest, Trunk, and/or Abdomen

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.

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."

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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-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.

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.

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The trial of conservative therapy must be 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.

Six-Month Trial for Chronic Venous Insufficiency

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-E0652). This assessment may be performed by the prescribing physician 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 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.

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DOCUMENTATION REQUIREMENTS

General

For PCDs coded E0650 or E0651 the medical record must contain sufficient detailed and specific information to show that the applicable coverage criteria for I - LYMPHEDEMA or II - CHRONIC VENOUS INSUFFICIENCY WITH VENOUS STASIS ULCERS (CVI) are met.

For PCDs coded as E0652 the medical record must contain sufficient detailed and specific information to show that the applicable coverage criteria in III - LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN are met.

The documentation for each of the above must include careful, detailed records of measurements, obtained in the same manner and with reference to the same anatomic landmarks, prior to, at periodic times during and at the conclusion of the various trials and therapy, with bilateral comparisons where appropriate.

Certificate of Medical Necessity (CMN) (PIM 5.3)

A Certificate of Medical Necessity (CMN) which has been completed, signed, and dated by the treating practitioner must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the detailed written order if it contains the same information as required in a detailed written order. The CMN for pneumatic compression pumps is CMS Form 846 (DME Form 04.04B). The initial claim must include an electronic copy of the CMN. In addition to the order information that the practitioner enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the order or the treating practitioner can enter the other details directly.

If question #1 on the CMN ("Does the beneficiary have chronic venous insufficiency with venous stasis ulcers?") is answered "Yes", documentation reflecting all of the following must be in the beneficiary's medical record and made available upon request:

1. The location of venous stasis ulcer(s),
2. How long each ulcer has been continuously present,
3. Previous treatment with a COMPRESSION bandage system or COMPRESSION garment, appropriate dressings for the ulcer(s), exercise and limb elevation for at least the past 6 months,
4. Evidence of regular practitioner visits for treatment of venous stasis ulcer(s) during the past 6 months.

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

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BILLING GUIDELINES

If these pneumatic devices are billed for use during ambulatory surgery (POS 24) they will deny as not-covered to the facility fee.

Pneumatic Compression Device Code Selection (E0650-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- E0673) is considered functionally equivalent to an E0651 compressor with a segmented appliance/sleeve (E0667-E0669).

A 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.

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.

PCDs consist of an electrical pneumatic pump and an inflatable appliance that encloses the applicable body part. The pump fills the appliance with compressed air to predetermined pressures and intermittently alternates inflation and deflation to preset cycle times. The pressures and cycles vary between devices and, in some devices, are user-adjustable.

PCDs for the Treatment of Lymphedema or Chronic Venous Insufficiency (CVI) With Ulcers

PCDs used for the treatment of lymphedema or CVI with ulcers are coded based on the characteristics of the compression pump. The only HCPCS codes for PCDs used to treat lymphedema or CVI with ulcers are:

- E0650 - PNEUMATIC COMPRESSOR, NON-SEGMENTAL HOME MODEL
- E0651 - PNEUMATIC COMPRESSOR, SEGMENTAL HOME MODEL WITHOUT CALIBRATED GRADIENT PRESSURE

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E0652 - PNEUMATIC COMPRESSOR, SEGMENTAL HOME MODEL WITH CALIBRATED GRADIENT PRESSURE

The HCPCS codes used for the inflatable appliances used with PCDs E0650 - E0652 are:

- 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

A non-segmented pneumatic compressor (E0650) is a device that has a single outflow port on the compressor. Pressurized air from the single outflow port is transmitted to an appliance with single or multiple segments. The segment(s) inflate and deflate based on the compressor-specified pressure and cycle times. The number of segments contained in the appliance does not affect HCPCS coding of the compressor. Appliances appropriate for use with an E0650 PCD are E0655, E0660 - E0666, and E0671 - E0673.

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 segmented pneumatic compressor (E0651, E0652) is a device that has multiple outflow ports on the compressor. The pressurized air from each outflow ports is transmitted to corresponding segments on the appliance. The segments inflate and deflate based on the compressor-specified pressures and cycle times.

A segmented device without calibrated gradient pressure (E0651) is one in which either the same pressure is present in each segment or there is a predetermined pressure gradient in successive segments. E0651 PCDs cannot individually set or adjust pressures in separate appliance segments. In an E0651 PCD, the pressure is usually set by a single control on the distal segment. Appliances appropriate for use with an E0651 PCD are E0667-E0669.

A segmented device with calibrated gradient pressure (E0652) is characterized by manual control on at least three outflow ports that can deliver an individually determined pressure to each corresponding

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appliance segment. Use of tubing and/or appliances that can create a pressure gradient independently from the compressor does not qualify to classify the compressor as E0652. These methods are not considered as calibrated gradient pressure. Appliances appropriate for use with an E0652 PCD are E0656, E0657, and E0667 - E0670.

All limb appliances (E0655, E0660 - E0673) used with PCDs E0650 - E0652 must enclose the affected limb(s) sufficiently to prevent retrograde edema fluid flow (distally). All limb appliances (E0655, E0660 - E0673) used with PCDs E0650 - E0652 must avoid a tourniquet effect during compression that would prevent distal fluid from moving proximally. Appliances that create a tourniquet effect or cause retrograde flow of edema fluid must be coded A4600 - SLEEVE FOR INTERMITTENT LIMB COMPRESSION DEVICE, REPLACEMENT ONLY, EACH.

PCDs for the Treatment of Peripheral Artery Disease

The only HCPCS code for PCDs used for the treatment of peripheral artery disease is:

E0675 - PNEUMATIC COMPRESSION DEVICE, HIGH PRESSURE, RAPID INFLATION/DEFLATION CYCLE, FOR ARTERIAL INSUFFICIENCY (UNILATERAL AND BILATERAL SYSTEM)

The HCPCS codes used for the inflatable appliances used with PCD E0675 are:

- 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

An E0675 is a PCD that delivers high pressure and rapid inflation/deflation cycles for the treatment of arterial insufficiency (peripheral artery disease). HCPCS code E0675 is all-inclusive, i.e. all product variations in pressures, cycle characteristics, timing, control systems, appliance configurations, etc. (not all-inclusive) are considered as described by the code. Appliances appropriate for use with an E0675 PCD are E0667-E0669.

PCDs for Deep Venous Thrombosis (DVT)

Home intermittent pneumatic compression devices for the prevention of DVT are not covered for use at Ambulatory Surgery Centers. They are considered part of the facility fees and not separately reimbursable.

The only HCPCS code for PCDs used for the prevention of DVT is:

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

An E0676 is a PCD that delivers pressure and inflation/deflation cycles for the prevention of deep venous thrombosis. HCPCS code E0676 is all-inclusive, i.e. all product variations in pressures, cycle

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characteristics, timing, control systems, appliance configurations, etc. (not all-inclusive) are considered as described by the code.

The appliance(s) and any other accessories, options, and supplies used with PCD E0676 are included in the payment for HCPCS code E0676 at the time of initial issue and must not be billed separately to Medicare. If a supplier chooses to bill separately for these items at the time of initial issue, then HCPCS code A9900 - MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE must be used to bill Medicare for the item(s).

HCPCS code A4600 – SLEEVE FOR INTERMITTENT LIMB COMPRESSION DEVICE, REPLACEMENT ONLY, EACH is used only when the appliance used with an E0676 device is being replaced. HCPCS codes E0655 - E0673 must not be used when billing for appliances used with E0676 devices.

Miscellaneous

When a foot or hand segment is used in conjunction with any leg or arm appliance respectively, there must be no separate billing for this segment. It is considered included in the code for the leg or arm appliance.

The only products that may be billed to the DME MACs using codes E0650, E0651, E0652 and E0675 are those for which the Pricing, Data Analysis, and Coding (PDAC) contractor has completed a Coding Verification Review. The coding determination subsequently is 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.

HCPCS CODES

All Lines of Business Except Medicare	
No Prior Authorization Required	
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

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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
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
Not Covered	
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)

REVIEW OF EVIDENCE

The use of pneumatic compression devices for the treatment of lymphedema and chronic venous insufficiency is based on Centers for Medicare & Medicaid Services guidance; therefore, an evidence review is not included for these indications.

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of pneumatic compression devices for the prevention of deep vein thrombosis. Below is a summary of the available evidence identified through March of 2020.

Systematic Reviews

In 2020, Hayes updated a health technology assessment with an evidence review to evaluate pneumatic compression for the prevention of deep vein thrombosis following knee surgery.⁵ The available evidence suggested that pneumatic compression may be effective in reducing the incidence of deep vein thrombosis (DVT) in patients who have undergone knee surgery, particularly when used in combination with other mechanical or pharmacological interventions for prevention of DVT. However, the available studies provide limited and somewhat inconsistent evidence concerning the efficacy of pneumatic compression relative to other strategies for DVT prevention and the optimal DVT prevention strategy for knee surgery patients remains unclear. Pneumatic compression therapy is reasonably safe and caused minor or no complications in the reviewed studies. Additional randomized trials are needed to determine the optimal strategy for DVT prevention, particularly in patients who cannot tolerate treatment with anticoagulants such as low-molecular-weight heparin (LMWH) and aspirin.

Therefore, based on the currently available published evidence, the following Hayes Ratings are assigned:

- “C – For pneumatic compression as an adjunct to LMWH for prevention of DVT after knee surgery. This rating reflects the similar safety profiles, but conflicting evidence regarding the efficacy of these approaches.

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- **C** – For pneumatic compression as an alternative to warfarin (Coumadin) for prevention of DVT after knee surgery. This rating reflects consistent but limited evidence that these approaches have similar safety and efficacy for prevention of DVT.
- **D2** – For pneumatic compression therapy alone as an alternative to LMWH alone for DVT prevention after knee surgery. This Rating reflects findings from a small body of conflicting evidence, some of which indicate that pneumatic compression therapy is less effective than LMWH.
- **D2**- For pneumatic compression therapy as an alternative to aspirin, graduated compression stockings, or continuous passive motion therapy for DVT prevention. There is insufficient high-quality evidence to determine the relative efficacy and safety of these treatment approaches.
- **D2**- For pneumatic compression therapy as an adjunct to aspirin, graduated compression stockings, or continuous passive motion therapy as alternatives to aspirin alone, compression stockings alone, or continuous passive motion therapy alone for DVT prevention, respectively.
- There is insufficient high-quality evidence to determine the relative efficacy and safety of these treatment approaches.”⁵

CLINICAL PRACTICE GUIDELINES

American College of Chest Physicians (ACCP)

The 2012 ACCP evidence-based guideline for the prevention of venous thromboembolism (VTE) in orthopedic surgery patients recommended the following regarding intermittent pneumatic compression devices:

- “In patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA), we recommend use of one of the following for a minimum of 10 to 14 days rather than no antithrombotic prophylaxis: low-molecular-weight heparin (LMWH), fondaparinux, apixaban, dabigatran, rivaroxaban, low-dose unfractionated heparin (LDUH), adjusted-dose vitamin K antagonist (VKA), aspirin (all Grade 1B), or an intermittent pneumatic compression device (IPCD) (Grade 1C).
- In patients undergoing hip fracture surgery (HFS), we recommend use of one of the following rather than no antithrombotic prophylaxis for a minimum of 10 to 14 days: LMWH, fondaparinux, LDUH, adjusted-dose VKA, aspirin (all Grade 1B), or an IPCD (Grade 1C).
- For patients undergoing major orthopedic surgery, we suggest extending thromboprophylaxis in the outpatient period for up to 35 days from the day of surgery rather than for only 10 to 14 days (Grade 2B).
- In patients undergoing major orthopedic surgery and increased risk of bleeding, we suggest using an IPCD or no prophylaxis rather than pharmacologic treatment (Grade 2C).”⁶

The 2012 AACP evidence-based guideline for the prevention of venous thromboembolism (VTE) in non-orthopedic surgical patients gave the following recommendations for intermittent pneumatic compression devices:

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- “For general and abdominal-pelvic surgery patients at low risk for VTE (~1.5%; Rogers score, 7-10; Caprini score, 1-2), we suggest mechanical prophylaxis, preferably with intermittent pneumatic compression (IPC), over no prophylaxis (Grade 2C).
- For general and abdominal-pelvic surgery patients at moderate risk for VTE (~3.0%; Rogers score, > 10; Caprini score, 3-4) who are not at high risk for major bleeding complications, we suggest low-molecular-weight heparin (LMWH) (Grade 2B), low-dose unfractionated heparin (LDUH) (Grade 2B), or mechanical prophylaxis, preferably with IPC (Grade 2C), over no prophylaxis.
- For general and abdominal-pelvic surgery patients at moderate risk for VTE (3.0%; Rogers score, > 10; Caprini score, 3-4) who are at high risk for major bleeding complications or those in whom the consequences of bleeding are thought to be particularly severe, we suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis (Grade 2C).
- For general and abdominal-pelvic surgery patients at high risk for VTE (~6.0%; Caprini score, ≥ 5) who are not at high risk for major bleeding complications, we recommend pharmacologic prophylaxis with LMWH (Grade 1B) or LDUH (Grade 1B) over no prophylaxis. We suggest that mechanical prophylaxis with elastic stockings (ES) or IPC should be added to pharmacologic prophylaxis (Grade 2C).
- For high-VTE-risk general and abdominal-pelvic surgery patients who are at high risk for major bleeding complications or those in whom the consequences of bleeding are thought to be particularly severe, we suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated (Grade 2C).
- For general and abdominal-pelvic surgery patients at high risk for VTE (6%; Caprini score, ≥ 5) in whom both LMWH and unfractionated heparin are contraindicated or unavailable and who are not at high risk for major bleeding complications, we suggest low-dose aspirin (Grade 2C), fondaparinux (Grade 2C), or mechanical prophylaxis, preferably with IPC (Grade 2C), over no prophylaxis.
- For cardiac surgery patients with an uncomplicated postoperative course, we suggest use of mechanical prophylaxis, preferably with optimally applied IPC, over either no prophylaxis (Grade 2C) or pharmacologic prophylaxis (Grade 2C).
- For cardiac surgery patients whose hospital course is prolonged by one or more nonhemorrhagic surgical complications, we suggest adding pharmacologic prophylaxis with LDUH or LMWH to mechanical prophylaxis (Grade 2C).
- For thoracic surgery patients at moderate risk for VTE who are not at high risk for perioperative bleeding, we suggest LDUH (Grade 2B), LMWH (Grade 2B), or mechanical prophylaxis with optimally applied IPC (Grade 2C) over no prophylaxis.
- For thoracic surgery patients at high risk for VTE who are not at high risk for perioperative bleeding, we suggest LDUH (Grade 1B) or LMWH (Grade 1B) over no prophylaxis. In addition, we suggest that mechanical prophylaxis with ES or IPC should be added to pharmacologic prophylaxis (Grade 2C).
- For thoracic surgery patients who are at high risk for major bleeding, we suggest use of mechanical prophylaxis, preferably with optimally applied IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated (Grade 2C).

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- For craniotomy patients, we suggest that mechanical prophylaxis, preferably with IPC, be used over no prophylaxis (Grade 2C) or pharmacologic prophylaxis (Grade 2C).
- For craniotomy patients at very high risk for VTE (eg, those undergoing craniotomy for malignant disease), we suggest adding pharmacologic prophylaxis to mechanical prophylaxis once adequate hemostasis is established and the risk of bleeding decreases (Grade 2C).
- For patients undergoing spinal surgery, we suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis (Grade 2C), unfractionated heparin (Grade 2C), or LMWH (Grade 2C).
- For patients undergoing spinal surgery at high risk for VTE (including those with malignant disease or those undergoing surgery with a combined anterior-posterior approach), we suggest adding pharmacologic prophylaxis to mechanical prophylaxis once adequate hemostasis is established and the risk of bleeding decreases (Grade 2C).
- For major trauma patients, we suggest use of LDUH (Grade 2C), LMWH (Grade 2C), or mechanical prophylaxis, preferably with IPC (Grade 2C), over no prophylaxis.
- For major trauma patients at high risk for VTE (including those with acute spinal cord injury, traumatic brain injury, and spinal surgery for trauma), we suggest adding mechanical prophylaxis to pharmacologic prophylaxis (Grade 2C) when not contraindicated by lower-extremity injury.
- For major trauma patients in whom LMWH and LDUH are contraindicated, we suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis (Grade 2C) when not contraindicated by lower-extremity injury. We suggest adding pharmacologic prophylaxis with either LMWH or LDUH when the risk of bleeding diminishes or the contraindication to heparin resolves (Grade 2C).⁷

American Academy of Orthopedic Surgeons (AAOS)

The 2012 AAOS evidence-based clinical practice guideline on preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty recommended the following regarding pneumatic compression devices:

- “We suggest the use of pharmacologic agents and/or mechanical compressive devices for the prevention of venous thromboembolism in patients undergoing elective hip or knee arthroplasty, and who are not at elevated risk beyond that of the surgery itself for venous thromboembolism or bleeding. Grade of Recommendation: Moderate
- Current evidence is unclear about which prophylactic strategy (or strategies) is/are optimal or suboptimal. Therefore, we are unable to recommend for or against specific prophylactics in these patients. Grade of Recommendation: Inconclusive
- In the absence of reliable evidence about how long to employ these prophylactic strategies, it is the opinion of this work group that patients and physicians discuss the duration of prophylaxis. Grade of Recommendation: Consensus
- In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who have also had a previous venous thromboembolism, receive pharmacologic prophylaxis and mechanical compressive devices. Grade of Recommendation: Consensus

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- In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who also have a known bleeding disorder (e.g., hemophilia) and/or active liver disease, use mechanical compressive devices for preventing venous thromboembolism. Grade of Recommendation: Consensus⁸

American College of Foot and Ankle Surgeons (ACFAS)

The 2015 ACFAS clinical consensus statement for the risk, prevention, and diagnosis of venous thromboembolism disease (VTED) in foot and ankle surgery and injuries requiring immobilization recommended a multimodal approach to VTED prophylaxis for patients at high risk. “This includes addressing any modifiable risk factors, using mechanical prophylaxis, early mobilization, and considering the use of chemical prophylaxis.”⁹

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

REFERENCES

1. Centers for Medicare & Medicaid Services National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6). Effective Date of this Version: 1/14/2002. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225>. Accessed 03/20/2020.
2. Centers for Medicare & Medicaid Services Local Coverage Article: Pneumatic Compression Devices - Policy Article (A52488). Revision Effective Date: 01/01/2020. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52488>. Accessed 03/20/2020.

MEDICAL POLICY**Compression: Outpatient Pneumatic Devices (All Lines of Business Except Medicare)**

3. Centers for Medicare & Medicaid Services Local Coverage Determination (LCD): Pneumatic Compression Devices (L33829). Revision Effective Date: For services performed on or after 01/01/2020. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33829>. Accessed 03/20/2020.
4. Centers for Medicare & Medicaid Services Local Coverage Article (LCA): A55426, Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs. Revision Effective Date: For services performed on or after 01/01/2020. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55426>. Accessed 03/20/2020.
5. McGrory BJ, Weber KL, Jevsevar DS, Sevarino K. Surgical Management of Osteoarthritis of the Knee: Evidence-based Guideline. *J Am Acad Orthop Surg*. 2016;24(8):e87-93. <https://www.ncbi.nlm.nih.gov/pubmed/27355286>
6. Falck-Ytter Y, Francis CW, Johanson NA, et al. Prevention of VTE in orthopedic surgery patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. 2012;141(2 Suppl):e278S-e325S.
7. Gould MK, Garcia DA, Wren SM, et al. Prevention of VTE in nonorthopedic surgical patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. 2012;141(2 Suppl):e227S-e277S.
8. Jacobs JJ, Mont MA, Bozic KJ, et al. American Academy of Orthopaedic Surgeons clinical practice guideline on: preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty. *The Journal of bone and joint surgery American volume*. 2012;94(8):746-747.
9. Fleischer AE AB, Baker JR, Boffeli TJ, Jupiter DC, Schade VL. American College of Foot and Ankle Surgeons' clinical consensus statement: risk, prevention, and diagnosis of venous thromboembolism disease in foot and ankle surgery and injuries requiring immobilization. *Journal of Foot and Ankle Surgery*. 2015;54(3):497-507.