Pneumatic Compression Devices for Lymphedema Treatment

[For the list of services and procedures that need preauthorization, please refer to www.mcs.com.pr, go to "Comunicados a Proveedores" and click "Cartas Circulares".]

Medical Policy:	**MP-DME-02-09**
Original Effective Date:	**February 5, 2009**
Revised:	**June 29, 2023**
Next Revision:	**June, 2024**

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider's contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member's benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

Pneumatic Compression Devices consist of an inflatable garment for the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary between devices.

Lymphedema is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. The accumulation of lymph fluid results from impairment to the normal clearing function of the lymphatic system and/or from excessive production of lymph. It is divided into two broad classes according to etiology:

1) **Defective development** of the lymphatic system (primary lymphedema) a relatively uncommon, chronic condition which may be due to Milroy's Disease[i] or congenital anomalies; and

2) **Secondary lymphedema,** which is much more common, results from the destruction or damage to formerly functioning lymphatic channels, such as radical surgical procedures with removal or regional groups of lymph nodes (for example, after radical mastectomy), post-radiation fibrosis, and spreading of malignant tumors to regional lymph nodes with lymphatic obstruction, among other causes.

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.

Lymphedema Sleeves – also referred to as compression garments or pressure sleeves, have been widely used in the treatment of lymphedema. They are used alone or in conjunction with other treatments, including lymphedema pumps and complex decongestive treatment (CDT). They are used for the purpose of preventing an increase in lymphedema and maintaining the reduction of lymphedema after treatment. They are custom fitted or prefabricated and have varying degrees of elasticity. The type of sleeve used is dependent on the size needed and whether the patient correctly fits the parameters of the prefabricated garment. The sleeve will usually need replacement when elasticity is lost, approximately every 4-6 months.

Lymphedema Pumps - Pneumatic compression pumps have been used as a treatment for lymphedema. Pumps may be classified as single chambered, multi chambered with fixed sequential inflation, or multi chambered with sequential inflation and manually calibrated gradient chamber pressure.

Established conservative medical treatments include the use of bandaging and compression garments, limb elevation, and home exercise programs. Segmental pumps that have a calibrated pressure feature are typically used only in patients who require limited pressure to be applied to a specific area (e.g., significant scars or the presence of contracture or pain caused by the clinical condition).

Types of Lymphedema Pumps
Lymphedema pumps include, but are not limited to the following:

- Non-segmented pneumatic compressor.
- Segmented pneumatic compressor; this device has multiple outflow ports on the compressor that lead to distinct segments on the appliance, which inflates in a sequential manner.
- A segmented device without calibrated pressure 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 not the ability to individually set, **or**
    c. Adjust pressures in each of the several segments. The pressure is usually set by a single control on the distal segment.
    d. A segmented device with calibrated gradient pressure is characterized by a manual control on at least three outflow ports than can deliver individually determined pressure to each segmental unit.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits, and coverage.

CONDITIONS FOR COVERAGE

Pneumatic compression devices will be covered **ONLY** when:

1. They are ordered and supervised by a physician (a Medical Doctor (MD), an Osteopathic Physician (DO), or a Doctor of Podiatric Medicine (DPM)) or physician extenders (Nurse Practitioner (NP), a Physician Assistant (PA), or a Clinical Nurse Specialist (CNS)) to the extent

allowed by their applicable 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.

2. For pneumatic compression devices in this policy to be covered, a Written Order Prior to Delivery (WOPD) is required, and the supplier must have received a signed Standard Written Order (SWO) before submitting a claim for any associated options, accessories and /or supplies that are separately billed. If the supplier bills for associated options, accessories, and/or supplies without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

INDICATIONS

Medical Card System, Inc., (MCS) will consider **medically necessary** the use of Pneumatic Compression Devices when **ONE** of the following conditions is met:

I. Pneumatic Compression Devices are covered in the home setting for the treatment of Lymphedema when:

1. The member has a diagnosis of lymphedema, **and**

2. The member has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings:

    a. Marked hyperkeratosis with hyperplasia and hyperpigmentation

    b. Papillomatosis cutis lymphostatica,

    c. Deformity of elephantiasis,

    d. Skin breakdown with persisting lymphorrhea,

    e. Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology.

3. 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.

The four-week trial of conservative therapy **must** include use all of the following:

a. 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.

b. Regular exercise

c. Elevation of the limb

II. Pneumatic Compression Devices are covered in the home setting for the treatment of Chronic Venous Insufficiency with Venous Stasis Ulcers (CVI) of the lower extremities only if the patient has all of the following:

1. Edema in the affected lower extremity

2. One or more venous stasis ulcer(s)

3. The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating physician.

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:

a. 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.

b. Medications as appropriate (e.g. diuretics and/or other treatment of congestive failure, etc.)

c. Regular exercise

d. Elevation of the limb

e. Appropriate wound care for the ulcer (including sharp debridement where appropriate).

III. Pneumatic Compression Devices are covered in the home setting for the treatment of lymphedema extending onto the chest, trunk and/or abdomen when:

1. The individual has unique characteristics that prevent them from receiving adequate 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.

    a. The beneficiary has lymphedema of an extremity as defined above.

    b. The coverage criteria in Section I or Section II are met.

    c. 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.

Four-Week Trial for lymphedema extending onto the chest, trunk and/or abdomen must include all the following:

a. At least four weeks of regular, daily, multiple-hour home usage of the pneumatic compression devices (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.

b. Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression (The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally).

c. Regular exercise and elevation where appropriate.

d. Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 30 minutes per day.

e. Evaluation of diet and implementation of any necessary change.

f. Medications as appropriate (e.g. diuretics and/or other treatment of congestive failure, etc.)

g. Correction (where possible) of anemia and/or hypoprotenemia.

CONTRAINDICATIONS

1. Relative contraindications to pneumatic compression are serious arterial insufficiency, edema due to congestive heart failure, active phlebitis, deep vein thrombosis, and the presence of localized wound infection or cellulitis.

LIMITATIONS

1. **Peripheral artery disease** - A Pneumatic Compression Device coded as E0675 to treat peripheral artery disease (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.

2. **Deep venous thrombosis prevention** - A Pneumatic Compression Device coded as E0676 will be only used for prevention of venous thrombosis.

3. The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650, E0651, and 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.

4 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.

5 For dates of service for which a Certificate of Medical Necessity (CMN) is required (Prior to January 1, 2023), a CMN which has been completed, signed, and dated by the treating practitioner and must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the standard written order (SWO) if it contains the same information as required in a SWO. The CMN for pneumatic compression pumps is CMS Form 846. For claims with dates of service on or after January 1, 2023 – Providers and suppliers no longer need to submit CMNs or DIFs with claims. Due to electronic filing requirements, claims received with these forms attached will be rejected and returned to the provider or supplier.

RATIONALE

MCS framework is designed to improve access, outcomes, and our enrollee's experience of care and to ensure all enrollees achieve their best health. This policy acts as a guideline for nursing staff in the initial screening of service requests, meticulously upholding a hierarchy that prioritizes Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) established by the Centers for Medicare & Medicaid Services (CMS), followed by our organization's medical policy, recognized medical association guidelines, and clinical decision-making processes. It is crafted to ensure that preliminary assessments are in harmony with these layers of guidance, underscoring that all final coverage determinations strictly adhere to the relevant LCDs and NCDs, while also considering the insights from recognized medical associations and the clinical judgment of healthcare professionals (MD's and DMD's) as necessary.

CODING INFORMATION

CPT® Codes (List may not be all inclusive)

CPT® Codes	DESCRIPTION
97016	Application of a modality to 1 or more areas; vasopneumatic devices

Current Procedural Terminology (CPT®) 2023 American Medical Association: Chicago, IL.

HCPCS CODES (List may not be all inclusive)

HCPCS® CODES	DESCRIPTION
A4600	Sleeve for intermittent limb compression device, replacement only, each
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS
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

2023 HCPCS LEVEL II Professional Edition® (American Medical Association).

HCPCS MODIFIER:
EY - No physician or other licensed health care provider order for this item or service.

NOTES FOR COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:

NOTE$_1$: LYMPHEDEMA:

1. 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 requirements described in Section I are met. Claims that do not meet all of the requirements will be denied as not reasonable and necessary.

2. 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.

3. 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 to the Indications Section III - Lymphedema extending onto the chest, trunk and/or abdomen and PCD code selection for additional information about the limited coverage for PCD coded as E0652.

NOTE$_2$: CHRONIC VENOUS INSUFFICIENCY WITH VENOUS STASIS ULCERS (CVI):

1. A PCD coded as E0650 or E0651 is covered for the treatment of CVI of the lower extremities only if the patient has all the conditions specified in the Indications Section II of this policy. Claims that do not meet all of the requirements will be denied as not reasonable and necessary.

2. 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.

2. 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 Indications Section III - Lymphedema extending onto the chest, trunk and/or abdomen and PCD Code Selection for additional information about the limited coverage for PCD coded as E0652.

NOTE$_3$: LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN:

1. A PCD coded as E0652 used to treat lymphedema extending onto the chest, trunk and/or abdomen or CVI that does not meet all of the requirements above is not eligible for reimbursement. Claims that do not meet all of the requirements will be denied as not reasonable and necessary.

NOTE$_4$: ACCESSORIES

1. 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) 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.

NOTE$_5$: PNEUMATIC COMPRESSION DEVICE PCD CODE SELECTION (E0650 - E0652, E0675, and E0676):

1. A pneumatic compression device 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).

2. A segmented, calibrated gradient pneumatic compression device (HCPCs code E0652) is only covered is when the individual has unique characteristics that prevent them from receiving adequate satisfactory pneumatic compression treatment using a nonsegmented device along with a segmented appliance or a segmented compression device without manual control of pressure in each chamber.

3. 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.

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

5. A PCD coded as E0676 is used only for prevention of venous thrombosis. Items that are used for a preventive service or function are excluded from coverage under the Medicare DME benefit.

ICD-10 Codes (List may not be all inclusive)

ICD -10 Codes	DESCRIPTION
I83.001	Varicose veins of unspecified lower extremity with ulcer of thigh
I83.002	Varicose veins of unspecified lower extremity with ulcer of calf
I83.003	Varicose veins of unspecified lower extremity with ulcer of ankle

I83.004	Varicose veins of unspecified lower extremity with ulcer of heel and midfoot
I83.005	Varicose veins of unspecified lower extremity with ulcer other part of foot
I83.008	Varicose veins of unspecified lower extremity with ulcer other part of lower leg
I83.011	Varicose veins of right lower extremity with ulcer of thigh
I83.012	Varicose veins of right lower extremity with ulcer of calf
I83.013	Varicose veins of right lower extremity with ulcer of ankle
I83.014	Varicose veins of right lower extremity with ulcer of heel and midfoot
I83.015	Varicose veins of right lower extremity with ulcer other part of foot
I83.018	Varicose veins of right lower extremity with ulcer other part of lower leg
I83.021	Varicose veins of left lower extremity with ulcer of thigh
I83.022	Varicose veins of left lower extremity with ulcer of calf
I83.023	Varicose veins of left lower extremity with ulcer of ankle
I83.024	Varicose veins of left lower extremity with ulcer of heel and midfoot
I83.025	Varicose veins of left lower extremity with ulcer other part of foot
I83.028	Varicose veins of left lower extremity with ulcer other part of lower leg
I83.10	Varicose veins of unspecified lower extremity with inflammation
I83.11	Varicose veins of right lower extremity with inflammation
I83.12	Varicose veins of left lower extremity with inflammation
I83.201	Varicose veins of unspecified lower extremity with both ulcer of thigh and inflammation
I83.202	Varicose veins of unspecified lower extremity with both ulcer of calf and inflammation
I83.203	Varicose veins of unspecified lower extremity with both ulcer of ankle and inflammation
I83.204	Varicose veins of unspecified lower extremity with both ulcer of heel and midfoot and inflammation
I83.205	Varicose veins of unspecified lower extremity with both ulcer other part of foot and inflammation
I83.208	Varicose veins of unspecified lower extremity with both ulcer of other part of lower extremity and inflammation
I83.211	Varicose veins of right lower extremity with both ulcer of thigh and inflammation
I83.212	Varicose veins of right lower extremity with both ulcer of calf and inflammation
I83.213	Varicose veins of right lower extremity with both ulcer of ankle and inflammation
I83.214	Varicose veins of right lower extremity with both ulcer of heel and midfoot and inflammation

I83.215	Varicose veins of right lower extremity with both ulcer other part of foot and inflammation
I83.218	Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation
I83.221	Varicose veins of left lower extremity with both ulcer of thigh and inflammation
I83.222	Varicose veins of left lower extremity with both ulcer of calf and inflammation
I83.223	Varicose veins of left lower extremity with both ulcer of ankle and inflammation
I83.224	Varicose veins of left lower extremity with both ulcer of heel and midfoot and inflammation
I83.225	Varicose veins of left lower extremity with both ulcer other part of foot and inflammation
I83.228	Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation
I87.011	Post thrombotic syndrome with ulcer of right lower extremity
I87.012	Post thrombotic syndrome with ulcer of left lower extremity
I87.013	Post thrombotic syndrome with ulcer of bilateral lower extremity
I87.019	Post thrombotic syndrome with ulcer of unspecified lower extremity
I87.031	Post thrombotic syndrome with ulcer and inflammation of right lower extremity
I87.032	Post thrombotic syndrome with ulcer and inflammation of left lower extremity
I87.033	Post thrombotic syndrome with ulcer and inflammation of bilateral lower extremity
I87.091	Post thrombotic syndrome with other complications of right lower extremity
I87.092	Post thrombotic syndrome with other complications of left lower extremity
I87.093	Post thrombotic syndrome with other complications of bilateral lower extremity
I87.311	Chronic venous hypertension (idiopathic) with ulcer of right lower extremity
I87.312	Chronic venous hypertension (idiopathic) with ulcer of left lower extremity
I87.313	Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity
I87.321	Chronic venous hypertension (idiopathic) with inflammation of right lower extremity
I87.322	Chronic venous hypertension (idiopathic) with inflammation of left lower extremity
I87.323	Chronic venous hypertension (idiopathic) with inflammation of bilateral lower extremity
I87.331	Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity
I87.332	Chronic venous hypertension (idiopathic) with ulcer and inflammation of left lower extremity
I87.333	Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity

I89.0	Lymphedema, not elsewhere classified
I89.1	Lymphangitis
I97.2	Postmastectomy lymphedema syndrome
Q82.0	Hereditary lymphedema

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POLICY HISTORY

DATE	ACTION	COMMENT
February 5, 2009	Origination of Policy	
February 18, 2010	Revised	I. Policy revised to add under indication #2, bullet "The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb". II. Under Contraindications/Limitations, the following was added: "Relative contraindications to pneumatic compression are significant arterial insufficiency, edema from congestive heart failure, active phlebitis, deep vein thrombosis, and the presence of localized wound infection or cellulitis". III. HCPCS and ICD-9 code list updated IV. References updated
February 18, 2011	Yearly Review	1. Reference updated Centers for Medicare and Medicaid Services. Cigna Government Services. Pneumatic Compression Devices. LCD L5017. Revision Effective Date: February 4, 2011. Accessed February 18, 2011.
March 16, 2012	Yearly Review	References updated Center for Medicare & Medicaid Services (CMS). CGS Administrators, LLC. Pneumatic Compression Devices. LCD L5017. Effective Date: 10/01/1993. Revision effective date. 08/05/2011. Deleted ICD-9 code 707.00 and 707.10
March 6, 2013	Revised	References updated. To Coding Information added ICD-9 Codes: 453.81 - 453.89.
February 26, 2014	Yearly Review	References updated. • To the HCPCS Section: code E0670 was added to the policy. • New ICD#10 section was added to the policy. • To the references section: New references (3, 10, 11 and 12) were added to the policy.
March 13, 2015	Yearly Review	References updated. <u>To the Description Section</u>: • <u>The Information described was reviewed and corroborated in the following documents</u>: 1. Centers of Medicare & Medicaid Services (CMS). Medicare Coverage Issue Manual, Transmittal 150, December 26, 2001. Section 60-16. Pneumatic Compression Devices. Accessed February 19, 2015. 2. Pam Stepham. What is a Compression Sleeve? Updated: December 04, 2014. Accessed February 19, 2015. 3. NLM Medical Advisory Committee. Position Statement of the National Lymphedema Network. Updated February 2011. Accessed February 19, 2015. <u>To the Coverage Section:</u> Limitations section was incorporated in the coverage description of this section.

		To the Experimental/Investigational Section: • **New Information corroborated and was added to this section: "Also, there is insufficient evidence in the published, scientific literature to support the effectiveness of pneumatic compression devices in the treatment of other conditions (e.g., arterial ischemic ulcers or diabetic neuropathic ulcers of the lower extremities."** **To the Coding Section:** • **New ICD-9 454.1 was added to the Policy.** • **New HCPCS (E0675, and E0676) were added to the Policy.** • **New HCPCS MODIFIER "EY" was added to the Policy** • **New Subsection COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY was enumerated and a title was added to identify this subsection.** **To the References Section:** • **New References (#4, 9, 10, 11, 14, 18, and 19) were added to the Policy.**
November 23, 2015	**Revised**	**To the coding section:** • **Eliminate ICD-9 codes since they are no longer valid for diagnosis classification.** • **Add new section of ICD-10 codes which are the valid diagnosis classification system since October 1, 2015.**
August 10, 2016	**Revised**	**To the Coverage Section:** • **Conditions for Coverage:** ➢ **Phrase "a Physicians (a medical doctor (MD), an osteopathic physician (DO), or a doctor of podiatric (DPM)) or a physician extender (Nurse Practitioner (NP), A physician assistant (PA), or A clinical nurse specialist (CNS))" was added to Condition #1.** ➢ **New Conditions #3 was added to the Policy.** **To the Indications Section:** **To the Indication #1:** • **Information in Indication #1 was adapted and organized according to the LCD L33829.** • **Phrase "Compression starting with the Minimum of 30 mm Hg distally" was added to the Indication 4A.** • **Sentence "(The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with the Minimum of 30 mm Hg distally)" was added to the Condition 4A.** • **Word "Regular" was added to Indication 4B.** **To the Indication #2:** • **Phrase "If the Patient has all of the following" was added to the Statement of the Indication #2.** • **Information was adapted and organized according to the LCD L33829.** **To the Indication #3:** ▪ **New Indication Section III was added to the Indications Section.** **To the Limitations/ Exclusions Section:** • **New Limitation for "Peripheral Artery Disease" was added to the Policy.** • **New Limitation for "Deep venous thrombosis prevention" was added to the Policy.** **To the Experimental/ Investigational Section:**

		• This Information was deleted from this Policy. To the Coding Information Section: • New HCPCS codes E0656 and E0657 were added to the Policy. To the notes for coverage indications, limitations and/or medical necessity Section: • New Notes #1 – 5 were added to the policy from the LCD L33829. • The notes contained in the past revisions were deleted and adapted to the New LCD L33829. To the References Section: • New References #11 and 12 were added to the Policy. • References #8, 16 and 17 were deleted from the Policy.
December 13, 2016	MAC Final Approval	This Medical policy was discussed with MAC members and they approve the changes proposed.
May 8, 2018	Revised	References Updated. To the Description Section: • To 2nd definition, #2: Deleted word "it" and added comma. • To 4th definition – Added phrase "also referred to as", and term "pressure". To the Contraindications Section: • Replaced term "significant" with term "serious". To the Coding Information: • To Note 5, #2, bullet #1: replaced term no segmented with nonsegmented.
June 24, 2019	Revised	References Updated. Deleted #4 & #17. To the Conditions for Coverage Section: • To #1: Added term "Medicine" to Doctor of Podiatric DPM. Also added: "to the extent allowed by their applicable 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. Deleted: when are used with appropriate physician oversight, i.e., physician evaluation of the beneficiary'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, the frequency and duration of use, and ongoing monitoring of use and response to treatment. • Deleted #2: Pneumatic compression devices are ONLY covered for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers. If the coverage criteria below are not met the devices will be denied as not medically necessary. • To #3 Added: and the supplier must also obtain a Detailed Written Order (DWO) before submitting a claim for any associated options, accessories and /or supplies that are separately billed. If the supplier bills for associated options, accessories, and/or supplies without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary."

		To the Limitations Section: • **To #1: Added abbreviation "(PAD)".** **To the Coding Information Section:** • **Added HCPCS Codes: A9900 and A4600.** • **Added ICD-10 Code: I89.0**

April 24, 2020	**Revised**	**References updated.**
		
		To the Conditions for Coverage Section:
		• **Corrected former #3 to #2.**
		• **To #2 - Deleted: "also obtain a Detailed Written Order (DWO). Added: "have received a signed Standard Written Order (SWO). Replaced DWO with SWO.**
		
		To the Indications Section:
		• **To #3 – Deleted: "of an appropriate". Added: "all of the following.**
		• **To #3: Reworded bullet #3 to read as follows: a. 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.**
		• **To Indications Set III: To #1-c: Deleted: 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. Added: 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.**
		
		To the Coding Information Section:
		• **Deleted ICD-10 Codes: I82.609, I82.619, I82.629, I82.90, I82.91, I82.A19, I82.B19, I82.C19, I83.009, I83.019, I83.029, I83.209, I83.219, I83.229, I87.039, I87.099, I87.319, I87.329, I87.339, L97.101, L97.102, L97.103, L97.104, L97.109, L97.201, L97.202, L97.203, L97.204, L97.209, L97.301, L97.302, L97.303, L97.304, L97.309, L97.401, L97.402, L97.403, L97.404, L97.409.**
		• **Added ICD-10 Codes: I82.211, I82.291, I82.401, I82.402, I82.403, I82.411, I82.412, I82.413, I82.421, I82.422, I82.423, I82.431, I82.432, I82.433, I82.441, I82.442, I82.443, I82.491, I82.492, I82.493, I82.511, I82.512, I82.513, I82.521, I82.522, I82.523, I82.531, I82.532, I82.533, I82.541, I82.542, I82.543, I82.591, I82.592, I82.593**

April 08, 2021	**Revised**	**<u>To the Indications Section:</u>** **Word "Adequate" was added to the Indication III.1.** **<u>To the Contraindications Section:</u>** **Word "from" was deleted and substitute by the word "due to".** **<u>To the Limitations Section:</u>**

		New Limitations #3, 4, 5 and 6 were added to the Policy. **<u>To the Coding Information Section</u>:** • **<u>To the ICD-10 Codes Section</u>:** **<u>The following ICD-10 Codes were added to the Policy</u>:** **I97.12.** • **<u>The following ICD-10 Codes were deleted from this Policy</u>:** **I82.210, I82.211, I82.290, I82.291, I82.401, I82.402, I82.403, I82.411, I82.412, I82.413, I82.421, I82.422, I82.423, I82.431, I82.432, I82.433, I82.441, I82.442, I82.443, I82.491, I82.492, I82.493, I82.511, I82.512, I82.513, I82.521, I82.522, I82.523, I82.531, I82.532, I82.533, I82.541, I82.542, I82.543, I82.591, I82.592, I82.593, I82.601, I82.602, I82.603, I82.611, I82.612, I82.613, I82.621, I82.622, I82.623, I82.890, I82.A11, I82.A12, I82.A13, I82.B11, I82.B12, I82.B13, I82.C11, I82.C12, I82.C13, L97.111, L97.112, L97.113, L97.114, L97.119, L97.121, L97.122, L97.123, L97.124, L97.129, L97.211, L97.212, L97.213, L97.214, L97.219, L97.221, L97.222, L97.223, L97.224, L97.229, L97.311, L97.312, L97.313, L97.314, L97.319, L97.321, L97.322, L97.323, L97.324, L97.329, L97.411, L97.412, L97.413, L97.414, L97.419, L97.421, L97.422, L97.423, L97.424, L97.429, L97.501, L97.502, L97.503, L97.504, L97.509, L97.511, L97.512, L97.513, L97.514, L97.519, L97.521, L97.522, L97.523, L97.524, L97.529, L97.801, L97.802, L97.803, L97.804, L97.809, L97.811, L97.812, L97.813, L97.814, L97.819, L97.821, L97.822, L97.823, L97.824, and L97.829** **Word "adequate" was added NOTE5 #2.** **<u>To the References Section</u>:** • **<u>The following References were deleted from this Policy</u>:** **#3.**
March 15, 2022	**Revised**	**<u>To the Coding Information Section</u>:** • **<u>To the ICD-10 Codes Section</u>:** **<u>The following ICD-10 Codes were added to the Policy</u>:** **N/A.** • **<u>The following ICD-10 Codes were deleted from this Policy</u>:** **I70.231, I70.232, I70.233, I70.234, I70.235, I70.238, I70.239, I70.241, I70.242, I70.243, I70.244, I70.245, I70.248, I70.249, I70.331, I70.332, I70.333, I70.334, I70.335, I70.338, I70.339, I70.341, I70.342, I70.343, I70.344, I70.345, I70.348, I70.349, I70.431, I70.432, I70.433, I70.434, I70.435, I70.438, I70.439, I70.441, I70.442, I70.443, I70.444, I70.445, I70.448, I70.449, I70.531, I70.532, I70.533, I70.534, I70.535, I70.538, I70.539, I70.541, I70.542, I70.543, I70.544, I70.545, I70.548, I70.549, I70.631, I70.632, I70.633, I70.634, I70.635, I70.638, I70.639, I70.641, I70.642, I70.643, I70.644, I70.645, I70.648, I70.649, I70.731, I70.732, I70.733, I70.734, I70.735, I70.738, I70.739, I70.741, I70.742, I70.743, I70.744, I70.745, I70.748, and I70.749.** **<u>To the References Section</u>:** **No changes to the References. They were Update.**
June 29, 2023	**Revised**	**References updated.** **To the Limitations Section:** • To #4, last sentence; Deleted phrase "When and". • Modified limitation #6, which now reads: "For dates of service for which a Certificate of Medical Necessity (CMN) is required (Prior to January 1, 2023), a CMN which has been completed, signed, and dated by the treating practitioner and must be kept

		on file by the supplier and made available upon request. The CMN may act as a substitute for the standard written order (SWO) if it contains the same information as required in a SWO. The CMN for pneumatic compression pumps is CMS Form 846. For claims with dates of service on or after January 1, 2023 – Providers and suppliers no longer need to submit CMNs or DIFs with claims. Due to electronic filing requirements, claims received with these forms attached will be rejected and returned to the provider or supplier." **To the Notes For Coverage Indications, Limitation And/or Medical Necessity Section:** • Removed heading statement to former note #2.which read: "A PCD coded as E0652 has limited coverage. The NCD for Pneumatic Compression Devices (IOM 100-03, §280.6) provides:" • To note #2: Bullets were given new numbers 2 and 3 respectively. • Former #3 was changed to #4 and former #4 became new #5.
November 2, 2023	**Revised**	**Some references were updated.** **To the Limitations Section:** • **Deleted #4:** 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. **To the Notes for Coverage, indications, limitations and/or medical necessity Section:** • Under Note 1: Lymphedema: Deleted note 2 and Added statement to Note 1, which reads as follows: Claims that do not meet all of the requirements will be denied as not reasonable and necessary. • Under note 2: for Chronic Venous Insufficiency with venous stasis ulcers (CVI): Deleted note 2 and Added statement to Note 1, which reads as follows: Claims that do not meet all of the requirements will be denied as not reasonable and necessary. • Under note 3 for Lymphedema Extending Onto The Chest, Trunk and/or Abdomen: Deleted note 2 and Added statement to Note 1, which reads as follows: Claims that do not meet all of the requirements will be denied as not reasonable and necessary. To the Coding Information Section: • Deleted HCPCS Codes E0675 & E0676, since there are non-covered as per Limitations Section.
April 11, 2024	**UMC Approval**	

[i] **Milroy's disease** is a familial disease characterized by lymphedema, commonly in the legs, caused by congenital abnormalities in the lymphatic system. Disruption of the normal drainage of lymph leads to fluid accumulation and hypertrophy of soft tissues. It is also known as **Milroy disease**, **None-Milroy-Meige syndrome** and **hereditary lymphedema.**