Molina Clinical Policy
Non-Pneumatic Compression Devices for Lymphedema:MEDICARE
Policy No. 490b

Initial Approval: 10/21/2026
Next Review Due By: October 2027

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment. Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the Federal government or CMS for Medicare. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Lymphedema is the abnormal collection of interstitial fluid and fibroadipose tissue due to impaired lymph transport. This condition can be primary, resulting from congenital abnormalities of the lymphatic system, or secondary in nature, resulting from trauma, infection, cancer treatments, or chronic disease (e.g., chronic venous insufficiency). Lymphedema typically presents unilateral in nature and can affect either the upper or lower extremities. Due to the resulting limb swelling, lymphedema affects patients' quality of life, as it is often accompanied by redness, itching, pain, tenderness, and negative self-image. Often, as the condition worsens, lymphedema can hinder mobility and function in the affected limb(s), further reducing independence and quality of life (Ashinoff et al. 2025; [1]Mehrara et al. 2025).

Lymphedema is predominantly treated through conservative therapy utilizing a multimodal approach called complete decongestive therapy (CDT). CDT involves therapeutic exercise to help increase lymph movement, manual lymphatic drainage massage, and static compression garments. The initial phase of CDT involves physical therapy and trained massage professionals completing the therapy and patient education five days a week for about 2 weeks. This initial phase is followed by a maintenance phase in which the patient continues the exercises and massage themselves, in addition to general self-care measures (e.g., skin care, nail care, maintenance of healthy body weight).

If CDT is not successful in reducing limb volume and symptoms, active compression therapy is initiated. This typically involves pneumatic compression devices (PCDs). PCDs are compression garments that sequentially inflate from the distal-to-proximal direction to mechanically aid lymphatic drainage. PCDs are hooked up to programmable pumps, which necessitate patients to remain stationary while the therapy is being administered. There is limited guidance on optimal PCD therapy duration, but it typically consists of daily use of 90 minutes up to multiple hours. The requirement to remain stationary during treatment is an adherence barrier to PCD therapy ([2]Mehrara et al. 2025).

Non-pneumatic compression devices combine static compression, passive gradient sequential compression during ambulation, and active gradient sequential compression via a controller to aid in lymphatic drainage. The garment is designed in a way that static compression supports joint and muscle contraction, which enhances the natural lymph drainage produced while ambulating. Active sequential compression is achieved via shape memory alloy actuators that contract and relax based on pre-programmed settings to compress in the distal-to-proximal manner. The controller is battery powered and can be clipped to or carried by the patient. Likewise, the garment itself is only tethered to the controller, therefore the system allows for maximum portability and mobility while receiving active treatment. The controller is programmed via smart-phone app, and the pressure settings are set by the prescribing provider (Barfield et al. 2025; Hayes 2026).

Regulatory Status

The Dayspring (Koya Medical Inc.) non-pneumatic compression device received FDA clearance via the 510(k) pathway in 2021. It is classified as a compressible limb sleeve under product code JOW. The original clearance was under K210885, with subsequent indication expansions under K212287 (Dayspring Lite) and K223228.

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COVERAGE POLICY

Non-pneumatic compression devices (e.g., Dayspring) for the treatment of lymphedema may be **considered medically necessary** when ALL the following criteria are met:

1. Member is ≥18 years of age

2. Confirmed and symptomatic diagnosis of ANY of the following:
   a. Lower extremity lymphedema
   b. Breast cancer-related upper extremity lymphedema
   c. Phlebolymphedema of the lower extremities

3. Failure of conservative treatment to improve symptoms after at least four weeks of a complete decongestive therapy program, including ALL the following:
   a. Therapeutic exercises and limb elevation
   b. Manual lymphatic drainage
   c. Static compression garments

4. Absence of ALL the following contraindications:
   a. Severely impaired ambulation or mobility of affected extremity
   b. Pulmonary embolism or deep vein thrombosis within the previous 6 months
   c. Uncontrolled congestive heart failure
   d. Severe peripheral artery disease

DOCUMENTATION REQUIREMENTS: Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the Member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Lower extremity lymphedema

Randomized Controlled Trials

Barfield et al. (2025) conducted a prospective, randomized, crossover head-to-head study to evaluate the safety and efficacy of a nonpneumatic compression device (NPCD) vs an advanced pneumatic compression device (PCD) in treating lower extremity lymphedema. A total of 71 patients, 73% of which were female, that participated in the trial were analyzed. All were over 18 years of age with a confirmed diagnosis of primary or secondary unilateral or bilateral lower extremity lymphedema or phlebolymphedema and were currently adherent to conservative therapy. Notable exclusion criteria included presence of active cellulitis and open or partially healed wounds, cognitive or physical impairment that would interfere with use of the device (e.g., impaired mobility), lipedema, active or recurrent cancer, acute infection, acute thrombophlebitis, pulmonary embolism or deep vein thrombosis within the past 6 months, pulmonary edema, congestive heart failure, and chronic kidney disease with acute renal failure. Patient demographics included a mean age of 58.7 ± 1.8 years, and an average body mass index of 32.6 ± 1.1. Most of the patients (n = 60 [85%]) had secondary lower extremity lymphedema, with 18.3% presenting with stage I, 61.9% stage II, and 19.7% stage II. The mean duration of lymphedema was 8.1 ± 0.9 years, and 52.1% of patients had bilateral disease. Following an initial washout period of 30 days, in which no PCDs were utilized, participants were randomized to either the NPCD group or PCD group for 90 days. Following completion of these 90 days, another 30-day washout period was enforced, after which participants crossed over into the alternative device arm. Thus, all participants were exposed to 90 days of both NPCD and PCD. The primary endpoints were change in affected limb volume between baseline (day 0) and end of treatment (day 90) and Lymphedema Quality of Life Questionnaire (LYMQOL) scores. Treatment adherence was recorded in patient diaries and was calculated as the percentage of reported daily use over the treatment period. Daily use was defined as at least one hour of active use per day. Mean limb volume decrease difference between the

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two arms reached statistical significance (p < 0.005), with a mean limb volume decrease of 369.9 ± 68.19 mL (P < .05) and a median of 300.5 mL in the NPCD arm vs 83.1 ± 67.99 mL (P < .05) and a median of 62.0 mL for the PCD arm. LYMQOL score improvements of 1.01 ± 0.23 (P < .05) vs that of 0.17 ± 0.18 (P > .05) PCD were achieved. Treatment adherence favored NPCD use with a reported rate of 81.0% ± 4% with a median of 92% for NPCD and 49.0% ± 6.5% with a median of 46% for PCD. No adverse events were reported for either arm. Overall, the authors concluded that NPCD was safe, effective, and elicited greater adherence than PCD use. Limitations included lack of blinding, small sample size, and unintended bias present in cross over trials such as order of which device was first used and possible unforeseen carryover effect from one treatment arm to the comparator. Larger well-designed trials are needed to confirm these findings.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

[1]Rockson et al. (2022) conducted a non-randomized, open-label pilot study to evaluate the safety and effectiveness of NPCDs for lower extremity lymphedema. The primary endpoints were to assess quality of life via the LYMQOL and change in lower limb volume via tape measure-derived, sequential circumferential measurements obtained by independently trained Certified Lymphedema Therapists. A total of 18 participants completed the study, all with diagnosed lower extremity lymphedema and actively participated in complete decongestive therapy. Prior to the start of the study, all participants had a 30 day washout period in which PCDs were not utilized. Results revealed that the overall quality of life scores improved by 8% to 16% by study completion and reached statistical significance in addition to the total aggregate scores and scores for subscales for Function, Appearance, and Mood. Lower limb volume had a mean change in edema of − 427.1 cm3 (p < 0.001, 95% confidence interval = − 677, − 178), with an average edema reduction rate of 39.4% from study initiation to completion. No serious adverse events were reported. Authors concluded that NPCDs are safe and efficacious in the treatment of lower limb lymphedema. Study limitations include the lack of randomization and control design, lack of adherence data collected, and small sample size.

Breast cancer related lymphedema

Randomized Controlled Trials

[3]Rockson et al. (2022) conducted a prospective, randomized, crossover head-to-head study to evaluate the safety and efficacy of a NPCD vs a pneumatic compression device PCD in treating breast cancer related lymphedema of the upper extremities. A total of 50 patients, aged 29 - 84, that participated in the trial were analyzed. All had a confirmed diagnosis of secondary upper extremity lymphedema related to breast cancer. All participants had to be at least three months post their last cancer diagnosis, with the average interval since cancer-related treatment being 5 years. All patients remained symptomatic despite being adherent to conservative therapy and utilizing static compression garments at the time of enrollment. Notable exclusion criteria included presence of active cellulitis and open or partially healed wounds, cognitive or physical impairment that would interfere with use of the device (e.g., impaired mobility), lipedema, acute infection, acute thrombophlebitis, pulmonary embolism or deep vein thrombosis within the past 6 months, pulmonary edema, congestive heart failure, and chronic kidney disease with acute renal failure. The mean time since the lymphedema diagnosis was 4.5 years. Following an initial washout period of 30 days, in which no PCDs were utilized, participants were randomized to either the NPCD group or PCD group for 90 days. Following completion of these 90 days, another 30-day washout period was enforced, after which participants crossed over into the alternative device arm. Thus, all participants were exposed to 90 days of both NPCD and PCD. The primary endpoints were change in affected limb volume between baseline (day 0) and end of treatment (day 90) and LYMQOL scores. Treatment adherence was recorded in patient diaries and was calculated as the percentage of reported daily use over the treatment period, defined as at least one hour of active use a day. Mean limb volume decrease difference between the two arms reached statistical significance (p < 0.005), with a mean limb volume decrease in the affected arm of 64.6% versus 27.7% (95% CI, 4.80-60.14) with the PCD. LYMQOL overall score improvements of +2.44 (P < 0.001) vs that of −0.01 (P > 0.3843) PCD were achieved. Treatment adherence favored NPCD use with a reported rate of 95.6% ± 7% with the NPCD vs 49.8% ± 26% with the PCD. No adverse events were reported for either device. Overall, the authors concluded that NPCD was safe, effective, and elicited greater adherence than PCD use. Limitations included lack of blinding, small sample size, and unintended bias present in cross over trials such as order of which device was first used and possible unforeseen carryover effect from one treatment arm to the comparator. Larger well-designed trials are needed to confirm these findings.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

[2]Rockson et al. (2022) conducted a non-randomized, open-label pilot study to evaluate the safety and effectiveness of NPCDs for breast cancer related upper extremity lymphedema. The primary endpoints were to assess quality of life via the LYMQOL and change in upper extremity volume via sequential circumferential measurements. A total of 40

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participants completed the study, all with diagnosed unilateral breast cancer related upper extremity lymphedema and actively participated in complete decongestive therapy. Prior to the start of the study, all participants had a 30-day washout period in which PCDs were not utilized. Results revealed that the overall quality of life scores improved 1.3 points (18%, $p < 0.001$) from baseline (7.05 ± 1.41) to study completion (8.33 ± 1.22). Treatment arm limb volume decreased on average by 2% (range of 1% to 12%) from baseline to study completion. Adherence to NPCD therapy was 98%, defined as use of at least 45 minutes daily for 28 days. Patient with experience using PCDs had a high preference rate in favor of NCPDs at 93% preferring the Dayspring device. No serious adverse events were reported. Authors concluded that NPCDs are safe and efficacious in the treatment of breast cancer related upper extremity lymphedema. Study limitations include the lack of randomization and control design, and small sample size.

National and Specialty Organizations

The **American Venous Forum** and the **American Venous and Lymphatic Society** published the position statement *Non-pneumatic compression and its clinical utility in management of lymphedema* (Jacobowitz et al. 2026). The position statement supports the incorporation of non-pneumatic compression devices in the care management of lymphedema due to its patient-centric treatment, as it reduces barriers to adherence while simultaneously improving patient outcomes. Non-pneumatic compression devices should be considered only after conservative treatment failure and in patients without impaired ambulation capability.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
E0677	Nonpneumatic sequential compression garment, trunk
E0678	Nonpneumatic sequential compression garment, full leg
E0679	Nonpneumatic sequential compression garment, half leg
E0680	Nonpneumatic compression controller with sequential calibrated gradient pressure
E0681	Nonpneumatic compression controller without calibrated gradient pressure
E0682	Nonpneumatic sequential compression garment, full arm
E0683	Nonpneumatic, nonsequential, peristaltic wave compression pump

CODING DISCLAIMER: Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/21/2026 New policy. IRO peer reviewed on October 1, 2026, by a practicing physician board certified in Family Medicine.

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