Clinical Policy: Treatment for Peripheral Lymphedema

Reference Number: CP.MP.198 Coding Implications
Last Review Date: 10/20 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.[1]

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that pneumatic compression devices (lymphedema pumps) are **medically necessary** for the treatment of lymphedema after failure of a four-week trial of conservative medical management including all of the following:
   A. Home exercise program;
   B. Limb elevation;
   C. Compression bandage or compression garment use.

II. It is the policy of health plans affiliated with Centene Corporation® that pneumatic compression devices are **medically necessary** for the treatement of chronic venous insufficiency with venous statis ulcers when meeting the following:
   A. One or more venous stasis ulcer(s) that have failed to heal after a six month trial of conservative therapy including all of the following:
      1. Use of a compression bandage system or compression garment;
      2. Appropriate dressings for the wound;
      3. Exercise;
      4. Elevation of the limb.

III. It is the policy of health plans affiliated with Centene Corporation® that over the counter (non-prescription) lymphedema compression sleeves are **not medically necessary.**

IV. It is the policy of health plans affiliated with Centene Corporation® that the following are considered experimental/investigational for the treatment of lymphedema:
   A. Two-phase lymph preparation and drainage therapy devices (e.g., Flexitouch® Lymphedema System);
   B. Microsurgical lymphaticovenous anastomosis. The long-term effectiveness of this procedure has not been established in the scientific literature.

Background
Lymphedema is an accumulation of lymphatic fluid in the interstitial tissue, principally in the subcutaneous fatty issues. The condition is marked by an abnormal collection of excess tissue proteins, edema, chronic inflammation, and fibrosis. Fluid accumulation results in gradual and progressive enlargement of the affected extremity or other region of the body accompanied with declines in functional and immunological capabilities, increased weight, and morphological

changes. Lymphedema is a frequent complication of cancer and its treatments, and the condition can have long-term physical and psychological consequences. It is typically a progressive and debilitating condition with no known cure. The reported incidence of lymphedema varies due to discrepancies in its definition and classification, measurement of affected areas, and other factors. In the United States, the highest incidence of lymphedema is observed among patients who undergo breast cancer surgery, particularly among those who undergo radiation therapy following axillary lymphadenectomy. Among this patient population, estimates of lymphedema frequency range from 10% to 40%. Estimates of worldwide lymphedema cases range from 120 to 250 million, with lymphedema filariasis being the most common type.

Pneumatic compression devices are commonly used for the treatment of acute and chronic peripheral lymphedema to facilitate the mobilization of fluid from the limbs into the trunk and central body cavity. These devices have also been used in the treatment of venous stasis, venous and arterial ulcers, and for the prevention of deep vein thrombosis. Pneumatic compression devices generally 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 among devices. Designed for use in both the home and institutional settings, the devices are generally intended to assist patients suffering from peripheral and vascular disorders, including primary or secondary lymphedema. The devices are currently used in both the primary and adjunctive treatment of lymphedema.[4]

Chronic Venous Insufficiency with Venous Stasis Ulcers
Chronic venous insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers.

General Coverage Criteria from Centers for Medicare and Medicaid Services[1]
Pneumatic compression devices are covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment. The determination by the physician of the medical necessity of a pneumatic compression device must include:

- The patient's diagnosis and prognosis;
- Symptoms and objective findings, including measurements which establish the severity of the condition;
- The reason the device is required, including the treatments which have been tried and failed; and
- The clinical response to an initial treatment with the device. The clinical response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.

Compression Garmet[2]

Compression garments are fitted elastic knit two-way low-stretch garments designed to generate greater pressures distally than proximally, thereby promoting mobilization of the edema fluid. They deliver 20 to 50+ mmHg of pressure. They are used to provide maintenance therapy to prevent fluid reaccumulation.

Compression garmets require a prescription and they must be provided by a fitter with appropriate expertise. They are typically worn during waking hours, with compression bandaging at night, if necessary.

Compression Sleeves are available over the counter without a prescription. There is insufficient evidence that they are effective in treating lymphedema, though may be helpful in some cases, particularly for maintaining improvement after treatment.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
97016	Application of a modality to one or more areas; vasopneumatic devices
97140	Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction) one or more regions, each 15 minutes

HCPCS© Codes	Description
A6530	Gradient compression stocking, below knee, 18-30 mm Hg, each
A6531	Gradient compression stocking, below knee, 30-40 mm Hg, each
A6532	Gradient compression stocking, below knee, 40-50 mm Hg, each
A6533	Gradient compression stocking, thigh length, 18-30 mm Hg, each
A6534	Gradient compression stocking, thigh length, 30-40 mm Hg, each
A6535	Gradient compression stocking, thigh length, 40-50 mm Hg, each
A6536	Gradient compression stocking, full length/chap style, 18-30 mm Hg, each
A6537	Gradient compression stocking, full length/chap style, 30-40 mm Hg, each
A6538	Gradient compression stocking, full length/chap style, 40-50 mm Hg, each
A6539	Gradient compression stocking, waist length, 18-30 mm Hg, each
A6540	Gradient compression stocking, waist length, 30-40 mm Hg, each
A6541	Gradient compression stocking, waist length, 40-50 mm Hg, each
A6544	Gradient compression stocking, garter belt
A6345	Gradient compression wrap, nonelastic, below knee, 30-50 mm Hg, each
A6549	Gradient compression stocking, not otherwise classified

HCPCS© Codes	Description
E0650	Pneumatic compressor, nonsegmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Nonsegmental 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
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0670	Segmental pneumatic appliance for use with pneumatic compressor, intergrated, 2 full legs and trunk
E0671	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg
S8420	Gradient pressure aid (sleeve and glove combination), custom made
S8421	Gradient pressure aid (sleeve and glove combination), ready made
8422	Gradient pressure aid (sleeve), custom made, medium weight
S8423	Gradient pressure aid (sleeve), custom made, heavy weight
S8424	Gradient pressure aid (sleeve), ready made
S8425	Gradient pressure aid (glove), custom made, medium
S8426	Gradient pressure aid (glove), custom made, heavy weight
S8427	Gradient pressure aid (glove), ready made
S8428	Gradient pressure aid (gauntlet), ready made
S8429	Gradient pressure exterior wrap
S8430	Padding for compression bandage, roll
S8431	Compression bandage, roll
S8950	Complex lymphedema therapy, each 15 minutes

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	02/11	02/11
Annual review, no changes	02/18	02/18
Annual review, no changes	02/19	02/19
Annual review, no changes	03/20	03/20
Minor wording changes with no clinical significance. Moved to Centene template from HS-078; renumbered to CP.MP.198. Replaced “member” with “member/enrollee” in all instances.	09/20	10/20

References

1. National coverage determination for pneumatic compression devices (280.6). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published January 14, 2002. Accessed September 28, 2020.

2. Mahara, B. Clinical staging and conservative management of peripheral lymphedema. UpToDate webside. www.uptodate.com. Published February 7, 2019. Accessed October 27, 2020.
3. Flexitouch® system (Tactile Systems Technology Inc.) for lymphedema. Hayes Directory Web site. http://www.hayesinc.com. Published June 30, 2017 (annual review November 26, 2019) Accessed September 28, 2020.
4. Microsurgical treatment of lymphedema following breast cancer surgery. Hayes Directory Web site. http://www.hayesinc.com. Published July 18, 2013 (archived on August 18, 2016). Accessed February 10, 2020.
5. Pneumatic compression devices for treatment of peripheral lymphedema. Hayes Directory Web site. http://www.hayesinc.com. Published June 6, 2005 (archived on January 9, 2009). Accessed February 10, 2020.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended

to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.