Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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Plan: AmeriHealth Caritas Pennsylvania	**Submission Date**: 1/1/2024
Policy Number: ccp.1326	**Effective Date:** 9/2017 **Revision Date:** December 1, 2023
Policy Name: Customized lymphedema garments	

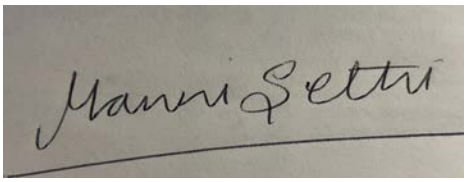
Type of Submission – Check all that apply:

x New Policy
Revised Policy*
Annual Review – No Revisions
Statewide PDL

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

New Policy See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Customized lymphedema garments

Clinical Policy ID: CCP.1326

Recent review date: 12/2023

Next review date: 4/2025

Policy contains: Compression bandaging, compression garments, customized, lymphedema garments.

AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania clinical policies are not guarantees of payment.

Coverage policy

Customized compression garments for lymphedema are clinically proven and, therefore, may be medically necessary when all of the following criteria are met (International Society of Lymphology, 2020; Health Share, 2016):

- Lymphedema has been diagnosed and documented by the treating physician.
- The condition impairs activities of daily living, limb use, safe transfers, or mobility.
- Any swelling from the lymphedema has been minimized.
- The affected area has been stabilized.
- No contraindications exist (see Limitations section).
- Garment is prescribed by a credentialed lymphedema expert or treating physician.

Each garment should be replaced every four to six months (or when the member's physical condition changes). Member must maintain two of each garment at all times, so one will always be available for use even when the other is being cleaned (National Comprehensive Cancer Network, 2023; Xiong, 2018).

Limitations

Contraindications to compression garment therapy include (International Society of Lymphology, 2020; Rabe, 2020):

- Severe peripheral arterial occlusive disease with an ankle brachial pressure index < 0.6, ankle pressure < 60 mm Hg, toe pressure < 30 mm Hg, or transcutaneous oxygen pressure < 20 mm Hg.

- Suspected compression of an existing epifascial arterial bypass.
- Severe cardiac insufficiency (New York Heart Association class IV).
- Routine application of medical compression in New York Heart Association class III cardiac insufficiency without a strict indication or clinical or hemodynamic monitoring.
- Confirmed allergy to compression material.
- Severe diabetic neuropathy with sensory loss or microangiopathy and with the risk of skin necrosis.

Alternative covered services

- Compression bandaging.
- Physical therapy.
- Drug therapy.
- Psychosocial rehabilitation.
- Surgery.

Background

Lymphedema is a swelling of lymph nodes from an excess of fluid, typically in the arms and legs. Symptoms include tightness and less flexible joints. The disorder represents a manifestation of lymphatic system insufficiency, as lymphatic transport is reduced (International Society of Lymphology, 2020).

Many cases of lymphedema occur after surgery to remove lymph nodes, often when treating various cancers. Among females treated for breast or gynecologic cancer, the risk approaches 40% (Johansson, 2015). Mastectomy and breast conserving surgery have higher rates of post-operative lymphedema than breast reconstruction (Siotos, 2018). The condition can also occur from medicines (such as tamoxifen), injury, or can develop spontaneously at birth, in puberty, and in adulthood.

The standard for diagnosing lymphedema has been through lymphangioscintigraphy, an intradermal injection in hands or feet that visualizes the lymphatic network and provides data on lymph transport using radioactive tracers. Genetic testing is becoming more common, and biopsy can be conducted in certain cases (International Society of Lymphology, 2020).

The International Society of Lymphology (2020) defines four stages of lymphedema that reflect the physical condition of the extremity. Providers may add functional severity assessment, limb volume measurement, and tonometry or fibrometry to further characterize tissue changes in lymphedema:

- Stage 0 represents the latent or subclinical condition when swelling is not yet evident despite impaired lymphatic transport.
- Stage I represents early fluid accumulation relatively high in protein content and often with the presence of pitting and an increase in the various types of proliferating cells.
- State II represents changes in solid structures and pitting for which limb elevation alone rarely reduces tissue swelling. In a later manifestation of Stage II, pitting may not occur as excess subcutaneous fat and fibrosis develop.
- Stage III encompasses lymphostatic elephantiasis with trophic skin changes such as acanthosis, alterations in skin character and thickness, further deposition of fat and fibrosis, and warty overgrowths. Pitting may be absent.

The initial phase of non-surgical lymphedema treatment begins with physical therapy, typically involving light manual massage, range of motion exercise, and compression applied with multi-layered bandage-wrapping. After physical therapy, use of low stretch elastic garments is essential to maintain lymphedema reduction. Drug therapy and psychosocial rehabilitation are also used. Surgery to alleviate lymphedema is sometimes performed, but is not yet accepted as the standard of practice (International Society of Lymphology, 2020).

Compression bandaging are multiple layers of bandages adjusted to patient need. They are an effective and flexible form of compression, especially in the early stages of treatment, and provide proper compression when the patient is active or resting. Bandages must be strategically applied with low-to-moderate tension using more layers in the distal portions of the affected limb(s). Interstitial cycling between low-resting and high-working pressures creates an internal pump that encourages movement of congested lymph along the distal to proximal gradient created by bandaging (Oncology Nursing Society, 2023). Compression bandaging can be burdensome and impractical for some patients, due to the dexterity required (Fu, 2014).

A compression garment is a knitted, two-way stretch sleeve or stocking worn to assist in controlling swelling and to aid in moving lymph fluid from the affected area. They are fabricated to apply specific pressure to a particular part of the body and should be custom fitted and prescribed according to the patient's ability to manage the garment to maintain the best volume control and skin health. In addition to the day garments used in the latter phases of treatment, some patients with more severe forms of lymphedema may require night garments or advanced day garments to maintain the reductions obtained soon after onset. The effectiveness of compression garments lasts four to six months and require replacement at the end of that time (Xiong, 2018).

Compression bandaging and compression garments may be used alone, together, or in combination with other forms of decongestive therapy (Finnane, 2015). For pediatric lymphedema, which almost always affects the lower extremities, compression garments are the sole treatment in 75% of the cases; only a small minority (13%) require surgical intervention (Schook, 2011).

Findings

A systematic review identified four clinical practice guidelines on lymphedema, excluding consensus and position statements. The four guidelines included Lymphedema Framework Best Practice for the Management of Lymphedema; Japanese Lymphedema Study Group-A Practice Guideline for the Management of Lymphedema; Clinical Resource Efficiency Support Team Guidelines for the Diagnosis, Assessment and Management of Lymphedema; and Guidelines of the American Venous Forum. However, only one of the four were based on systematic reviews after 2007 (O'Donnell, 2020).

The American Cancer Society recommends the use of compression garments in cancer survivors, along with progressive resistance training, under the supervision of a therapist (Rock, 2012), as did the International Union of Phlebology (Lee, 2013).

A 2016 guideline from Australia recommends compression garments for long-term management of lymphedema that severely limits activities of daily living, limb use, safe transfers, or mobility if: 1) the edema is stable; 2) swelling is minimized; 3) any shape or distortion is optimized; and 4) the affected area is stabilized. If ready-to-wear garments fail, custom-made garments can be used. The guideline recommends allocating two sets of garments per affected limb every six months (Health Share, 2016).

The National Comprehensive Cancer Network (2023) recommends compression garments as part of ongoing home management of lymphedema following cancer treatment. Compression garments should be prescribed and, optimally, fitted and measured by a certified lymphedema therapist. The fit and age of compression garments should be monitored and garments should be replaced when needed.

According to the International Society of Lymphology (2020), accurate, early diagnosis and available effective therapies allow for a more proactive approach to managing peripheral lymphedema. No type of lymphedema treatment has undergone a rigorous set of controlled trials or meta-analyses, and, thus, evolving expert clinical judgement will govern treatment of the disorder. There is consensus on the following points:

- Several manufactured devices and garments are available to assist in compression (i.e., pull on, velcro-assisted, quilted, etc.) as alternatives to more burdensome compression bandaging, which may enhance patient compliance with a full lymphedema treatment program.
- Custom elastic garments (with correctly-obtained specific measurement if needed) are essential to maintain lymphedema reduction after complex decongestive therapy for long-term care.
- Compression garments used alone are effective, particularly in breast cancer-related lymphedema, for prevention of fluid buildup and minimal volume change, and in early Stage I disease.
- The evidence on compression garments used alone for later stages is very limited.
- Compression garments should be prescribed to avoid inappropriate use in a patient with medical contraindications (e.g., arterial disease, painful post-phlebitic syndrome, occult neoplasia, acute infections, and certain skin disorders).
- Multilayer wrapping should be carried out only by professionally trained personnel.

While adverse events related to compression garment use are rare, an international consensus of experts listed the following main contraindications (Rabe, 2020):

- Severe peripheral arterial occlusive disease with ankle brachial pressure index < 0.6, ankle pressure < 60 mm Hg, toe pressure < 30 mm Hg, or transcutaneous oxygen pressure < 20 mm Hg.
- Suspected compression of an existing epifascial arterial bypass.
- Severe cardiac insufficiency (New York Heart Association class IV).
- Routine application of medical compression in New York Heart Association class III cardiac insufficiency without a strict indication and clinical and hemodynamic monitoring.
- Confirmed allergy to compression material.
- Severe diabetic neuropathy with sensory loss or microangiopathy with the risk of skin necrosis.

The evidence described in the following systematic reviews confirms these findings. A review of 26 studies (n = 1,018) identified a paucity of randomized controlled studies on the efficacy of all types of lymphedema therapy after head and neck cancer surgery (Tyker, 2019). A recent systematic review (n = 2,155) concluded there was no consensus on the definition or treatment of lymphedema after conservative breast surgery (Abouelazayem, 2021). A systematic review and network meta-analysis of 36 studies (n = 1,651) found conservative treatments did not significantly reduce lymphedema volume (Lytvyn, 2020).

Several other systematic reviews and meta-analyses of persons with lymphedema resulting from cancer surgery provided conflicting results on the efficacy of compression garments. One review of 25 studies (n = 1,018) showed a reduction in swelling after breast cancer surgery from use of compression garments and bandaging, based on moderate evidence (McNeely, 2011). Another review of 75 articles between 2009 and 2014 supported compression garments, compression bandages, and decongestion therapy with the “highest evidence for best practice” in reducing cancer-related lymphedema, but stated that more controlled trials are needed (Fu, 2014).

An article that included nine randomized controlled trials and 19 pre-post random effects studies used in a meta-analysis concluded that compression sleeves did not aid in reducing volume of edema in the acute phase for

female breast cancer patients with lymphedema, but were helpful in preventing additional swelling (Rogan, 2016). Another analysis of two controlled trials and five observational studies found that all treatments in cancer patients with lymphedema, including compression stockings, reduced volume of swelling (Leung, 2015).

A systematic review/meta-analysis of 25 studies addressing exercise for cancer-related lymphedema included only four studies of concurrent use of compression garments, and thus provided insufficient evidence to support or refute clinical recommendations to wear garments during exercise (Singh, 2016).

A study identified 37 of 201 (17%) of women who had worn lymphedema garments after breast cancer surgery had discontinued use within five years. Reasons for discontinuation included discomfort, and stable lymphedema. Subjects who discontinued garment use tended to believe that garments were not effective in managing their condition, reported greater levels of mild-moderate swelling, and had swelling for more than five years (Longhurst, 2018).

In 2022, we updated the references and added two new guidelines (National Comprehensive Cancer Network, 2022; Rabe, 2020). We added contraindications to the coverage limitations.

In 2023, we updated the references and added the results from a randomized controlled trial comparing the effectiveness of compression sleeves in women with early stage breast cancer who developed an early 4% to 9% relative arm volume increase within nine months following axillary clearance surgery. Participants were randomized to standard management (elevation, exercises, and self- massage (n = 74) or standard management plus graduated compression garments to the affected arm for 12 months (n = 69). There were no differences between groups in the lymphedema rate at 24 months (*P* = .32), time to development of lymphedema (hazard ratio adjusted for body mass index = 0.61, 0.34 to 1.1, *P* = .1), incidence of cellulitis (*P* = .12), incidence of moderate lymphedema (relative arm volume increase > 20%) within 24 months (*P* = .66). The authors questioned the value of compression sleeves in preventing lymphedema in this population (Bundred, 2023). No policy changes are warranted.

References

On September 22, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “compression garments,” “lymphedema garments,” and “lymphedema stockings.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

7/2017: initial review date and clinical policy effective date: 9/2017

8/2018: Policy references updated.

8/2019: Policy references updated. Policy ID changed to CCP.1326.

8/2020: Policy references updated.

8/2021: Policy references updated.

12/2022: Policy references updated. Title and coverage modified.

12/2023: Policy references updated.