Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 1/2/2025
Policy Number: ccp.1326	**Effective Date:** 9/2017 **Revision Date:** December 1, 2024
Policy Name: Customized lymphedema garments	

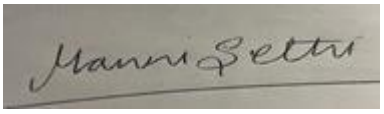
Type of Submission – Check all that apply:

- ☐ **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:

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: 12/2024

Next review date: 4/2026

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

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's 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 Keystone First- CHIP, on a case by case basis, 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. Keystone First- CHIP's 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. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's 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, 2023):

- 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).
- The 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, 2023; 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 manifestation of lymphatic system insufficiency and reduced lymphatic transport. Its characteristics are swelling of lymph nodes from an excess of fluid, typically in the extremities, which, if left untreated, can lead to skin and tissue changes and detriments to function, health, and quality of life. Swelling associated with lymphedema can occur anywhere in the body. Lymphedema is classified as either primary (genetic) or secondary (acquired). Secondary lymphedema results from injury or obstruction to the lymphatic system and affects approximately 1 in 1,000 Americans; the most common causes are cancer, cancer treatment, infection, and venous insufficiency (Sleigh, 2023).

Estimates of the prevalence of lymphedema vary widely, but a significant portion of patients treated for breast or gynecologic cancer receive care for lymphedema. In addition to the extent and location of the disease and treatment, common risk factors for developing lymphedema include a higher disease stage, overweight or obesity, Black race, and Hispanic ethnicity (National Cancer Institute, 2024).

Lymphedema is often confused with other causes of extremity edema and enlargement. The standard for diagnosing lymphedema is lymphoscintigraphy, an intradermal injection in hands or feet that visualizes the lymphatic network and provides data on lymph transport using radioactive tracers. Other imaging may be indicated to identify the cause (Sleigh, 2023). Genetic testing is becoming more common, and biopsy can be conducted in certain cases (International Society of Lymphology, 2023).
The International Society of Lymphology (2023) 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.
- Stage 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.

Regardless of stage at presentation, lymphedema is a progressive and incurable disease, and early diagnosis and intervention is critical. 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. Drug therapy and psychosocial rehabilitation are also used. Surgery to alleviate lymphedema is reserved for more severe cases (International Society of Lymphology, 2023).

Compression bandaging is an effective and flexible form of compression, especially in the early stages of treatment, but can be burdensome and impractical for some patients. 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 requires replacement at the end of that time (Xiong, 2018).

Findings

Guidelines

Guidance on use of compression garments for treating lymphedema are based on expert consensus. Compression garments are considered an important component of comprehensive decongestive therapy in the absence of medical contraindications.

The National Comprehensive Cancer Network (2024) recommends compression garments as part of ongoing home management of lymphedema following cancer treatment. Compression garments can reduce limb volume and are often used with other modalities such as manual lymphatic drainage, particularly in the early stages of lymphedema, when the condition is reversible. 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 (2023), accurate, early diagnosis and available effective therapies allow for a more proactive approach to managing peripheral lymphedema. Controlled trials of lymphedema treatment are limited, and evolving expert clinical judgement governs most recommendations for 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. The highest compression class tolerated (~20 to 60 mmHg) by the patient is likely to be the most beneficial.
- 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 lymphedema.
- 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.

A consensus guideline by the American Venous Forum, American Vein and Lymphatic Society, and the Society for Vascular Medicine states that regular use of compression garments reduces progression of lymphedema. There is a lack of consensus on the superiority of the type of compression garment. The choice of circular versus flat knit elastic compression will depend on the severity of lymphedema, limb shape, and patient compliance (Lurie, 2022).

Evidence review

The evidence described in the following systematic reviews confirms the consensus guidelines above. The effectiveness of lymphedema garments has been studied primarily in women following breast cancer surgery, but the results are conflicting, and more controlled trials and trials in patients with other types of cancer are needed. Moreover, a lack of consensus on the definition of and optimal treatment for lymphedema following conservative breast surgery hampers the certainty of findings (Abouelazayem, 2021).

A randomized controlled trial compared the effectiveness of compression sleeves in women with early stage breast cancer who developed a 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), or 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).

Data from 32 studies of low quality concluded that compression sleeves did not aid in reducing volume of edema in the acute phase but were helpful in preventing additional swelling (Rogan, 2016). In a study of 201 women who had worn lymphedema garments after breast cancer surgery, 37 (17%) had discontinued use within five years. Reasons for discontinuation included discomfort and stable lymphedema. Participants 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).

For head and neck lymphedema, complete decongestion therapy, which may combine manual lymphatic drainage, custom compression garments, physical exercise, and skin care, is often prescribed. A review of 26 studies (n = 1,018) identified a paucity of randomized controlled studies on the efficacy of all types of treatments of head and neck lymphedema following head and neck cancer surgery, particularly for complete decongestion therapy. The individual contribution of compression garments was not evaluated, but compression garments are often poorly tolerated (Tyker, 2019).

Another analysis of two controlled trials and five observational studies found that all treatments for patients with lower limb lymphedema from cancer, including compression stockings, reduced the volume of swelling (Leung, 2015). There is insufficient evidence to support or refute clinical recommendations to wear compression garments during exercise (Singh, 2016).

In 2022, we updated the references and added two new guidelines. We added contraindications to the coverage limitations.

In 2023, we updated the references. No policy changes are warranted.

In 2024, we updated the references and added new guideline information. No policy changes are warranted.

References

On October 11, 2024, 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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Xiong Y, Tao X. Compression garments for medical therapy and sports. *Polymers (Basel)*. 2018;10(6):663. Doi: 10.3390/polym10060663.

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.

12/2024: Policy references updated.