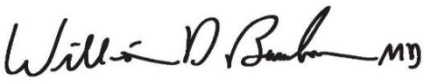
Prior Authorization Review Panel
MCO Policy Submission

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**: September 26, 2019
Policy Number: CCP.1326	**Effective Date:** September 1, 2017 **Revision Date:** September 10, 2019
Policy Name: 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:** Please see revisions below using tracked changes.	
Name of Authorized Individual (Please type or print): William D. Burnham, MD	**Signature of Authorized Individual:** 

Keystone First

Coverage by Vista Health Plan,
an independent licensee of the Blue Cross and Blue Shield Association.

Clinical Policy Title: Lymphedema garments

Clinical Policy Number: CCP.1326

Effective Date:	**September 1, 2017**
Initial Review Date:	July 20, 2017
Most Recent Review Date:	September 10, 2019
Next Review Date:	August 2020

Policy contains:

- Compression bandaging.
- Compression garments.
- Lymphedema garments.

ABOUT THIS POLICY: *Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First'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 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'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's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.*

Coverage policy

Compression garments for lymphedema are clinically proven and therefore medically necessary, under the following conditions:

- 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 (International Society of Lymphology, 2009; Health Share, 2016).

All care is to be coordinated by a credentialed lymphedema expert. Patients should replace each garment every four to six months (or when the patient's physical condition changes), and must maintain two of each garment at all times, so one will be always used even when one is being cleaned (National Lymphedema Network, 2017).

Limitations:

Compression garments that are not custom made under the supervision of a lymphedema expert are considered investigational and not medically necessary.

Alternative covered services:

None.

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, 2009).

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 percent (Johansson, 2015). 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 which 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, 2009).

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, 2009).

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. It should be worn only while the patient is awake and active and should be custom fitted. Compression bandaging is a form of compression used in the treatment of lymphedema. Bandages, which are multiple layers that are adjusted to patient need, are the most 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, 2017).

Garment style and compression strength should be prescribed according to the patient's ability to manage the garment and maintain the best volume control and skin health (National Lymphedema Network, 2017). In addition to the day garments used in the latter phases of treatment, some patients with more severe forms of lymphedema will require night garments or advanced day garments to maintain the reductions obtained soon after onset (National Lymphedema Network, 2017).

For pediatric lymphedema patients, which almost always affects the lower extremities, compression garments are the sole treatment in 75 percent of the cases; only a small minority (13 percent) require surgical intervention (Schook, 2011).

For mild lymphedema (stage 0 - 1), a compression sleeve or garment may be recommended, while complete decongestive therapy is recommended for stage 2 - 3 lymphedema to reduce swelling.

Compression bandaging can also be used for lymphedema. However, this treatment can become burdensome and not practical for some patients, due to the dexterity required, unlike the relative ease of simply wearing compression garments (Fu, 2014).

Among the types of garments used to treat lymphedema are 1) thromboembolic device hose that provide continuous pressure; 2) JOBST compression hosiery, a custom made garment to apply pressure to the upper limb, and 3) sequential compression devices, which are special pumps that push air into a sleeve. The general consensus for the order of using these devices is thromboembolic first, then JOBST, and finally sequential compression devices (Bhat, 2016).

Compression garments are one of the most commonly-used methods of treating lymphedema garments, along with self-massage, prescribed exercises, and manual lymph drainage. A self-administered questionnaire of 421 adults with lymphedema revealed that 95 percent used more than one form of treatment (Finnane, 2015).

Searches

We searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- The Cochrane reviews.

We conducted searches on June 20, 2019. Search terms were: "compression garments," "lymphedema garments," and "lymphedema stockings."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

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). The National Lymphedema Network asserts that compression garments must be replaced every four to six months to be effective. Garments are always part of combined decongestive therapy just after lymphedema appears post-operatively, after maximum volume reduction; they may also be used (National Lymphedema Network, 2017).

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 (Health Share, 2016).

A 2008 guideline from the American College of Chest Physicians includes use of compression stockings for persons traveling long distance (Geerts, 2008). The National Comprehensive Cancer Network guideline recommends use of compression stockings with a venous compression device (Streiff, 2010).

In a clinical guideline, the International Society of Lymphology asserts that 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 (International Society of Lymphology, 2013). Several guidelines from the Society, on lymphedema evaluation and management, were published from 1995 to 2016 (International Society of Lymphology, 2016).

A 2007 review of the literature declared compression garments the “mainstay” of treatment in lymphedema, along with intensive bandaging and lymphatic massage (Warren, 2007). However, in early 2010, a review found that no controlled trials had yet investigated effectiveness of compression sleeves for lymphedema after auxiliary node dissection for breast cancer (Devoogdt, 2010). A recent review of

26 studies (n = 1018) of treatment after head and neck surgery identified a paucity of randomized controlled studies on the efficacy of all types of lymphedema therapy (Tyker, 2019).

Several systematic reviews of persons with lymphedema resulting from cancer surgery addressed efficacy of compression garments. One review of 25 studies (n = 1018) 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 do not aid in reducing volume of edema in the acute phase for female breast cancer patients with lymphedema, but are 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 literature review of 51 studies evaluated medical compression stockings. Findings included moderately robust evidence for patients with venous symptoms and prevention/treatment of venous edema; robust evidence for prevention and treatment of venous leg ulcers; and evidence after great saphenous vein interventions limited to one week (Rabe, 2018).

A Cochrane review of 10 studies (n = 2361) evaluated effectiveness of elastic compression stockings on post-thrombotic syndrome, a long-term complication of deep vein thrombosis. Low-quality evidence suggests stockings reduce thrombosis risk, with no serious adverse effects (Appelen, 2017).

A meta-analysis of 27 studies addressed the safety and efficacy of microsurgery for lymphedema. A large proportion (91.2 percent) of patients reported subjective improvement after surgery, and 64.8 percent of patients discontinued compression garments at follow-up. Significant reductions were observed in excess and absolute circumference (48.8 percent and average 3.31 centimeters), and excess and absolute volume (56.6 and 23.1 percent) (Basta, 2014).

A systematic review and meta-analysis of 23 studies analyzed effects of compression garments on lower limbs during high-intensity exercise for adults age 18 and older. Users of compression garments showed no significant differences with controls for vertical jump height, maximal oxygen uptake, submaximal oxygen uptake, blood lactate concentrations, and ratings of perceived exertion (da Silva, 2018).

Some randomized controlled trials involving compression garment for lymphedema provide useful information, including:

- Of 803 patients with primary lower extremity lymphedema, those who used compression garments were significantly less likely to have self-reported pain, poor range of motion, and numbness (Deng, 2015).
- Of 95 women with lymphedema six weeks after breast cancer surgery, compression garments reduced excess arm volume by 22.6 percent, compared to 29.0 percent for daily manual lymphatic drainage and bandaging, an insignificant difference; improvements in arm function and quality of life were not significantly different as well (Dayes, 2013).
- Of 170 patients with lower lymphedema, those with compression garments were 2.85 times more likely to be satisfied than those not using them, compared to just 2.26 times for patients with simple lymphatic drainage (Iuchi, 2015).
- Of 86 pediatric patients with lymphedema, compression garments were used in 99 percent of cases, compared to 97 percent for manual lymph drainage and 68 percent for multilayered bandaging (Watt, 2017).
- All conservative therapies, including compression garments, for arm lymphedema produced relatively small improvements in arm symptoms and quality of life (Moseley, 2007).
- For female breast cancer patients with lymphedema, differences in effects of stem cell therapy could not be discerned from those of compression sleeves (Li, 2016).

A study identified 37 of 201 (17 percent) 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 over five years (Longhurst, 2018).

Policy updates:

The policy number was changed from CP#14.02.11 to CCP.1326 in June, 2019.

A total of two peer-reviewed references were added to, and one guideline/other and one peer-reviewed reference removed from this policy in June 2019.

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Professional society guidelines/other:

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Centers for Medicare & Medicaid National Coverage Determinations:

No National Coverage Determinations identified as of the writing of this policy.

Local Coverage Determinations:

No Local Coverage Determinations identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comments
97016	Application of a modality to 1 or more areas; vasopneumatic devices	
97140	Manual therapy techniques (e.g. mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes	

ICD-10 Code	Description	Comments
I89.0 - I89.9	Other noninfective disorders of lymphatic vessels and lymph nodes [intractable lymphedema]	
I97.2	Postmastectomy lymphedema syndrome	
I97.89	Other postprocedural complications and disorders of the circulatory system, not elsewhere classified	
Q82.0	Hereditary lymphedema	

HCPCS Level II Code	Description	Comments
S8420	Gradient pressure aid (sleeve and glove combination), custom made	
S8422	Gradient pressure aid (sleeve), custom made, medium weight	
S8423	Gradient pressure aid (sleeve), custom made, heavy weight	
S8425	Gradient pressure aid (glove), custom made, medium weight	
S8426	Gradient pressure aid (glove), custom made, heavy weight	
S8429	Gradient pressure exterior wrap	
S8950	Complex lymphedema therapy, each 15 minutes	

Appendix

No additional information was identified for this section during the writing of this policy.