Healthy Blue

Clinical UM Guideline

Subject:	Compression Devices for Lymphedema		
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Description

This document addresses the use of devices that create compression for the treatment of lymphedema. This therapy involves the use of garments designed for various body parts and include mechanisms intended to compress specific body parts targeted for treatment. Compression devices may be used in clinics or can be purchased or rented for home use. This document addresses the *home use* of compression devices used to treat lymphedema.

Note: This document addresses devices for the treatment of *lymphedema only*. Compression devices used in the treatment or prevention of venous thrombosis, venous insufficiency with refractory edema or ulceration, and therapy for musculoskeletal injury are **NOT** addressed in this document. For information regarding the use of compression devices for other indications please see:

- CG-DME-46 Pneumatic Compression Devices for Prevention of Deep Vein Thrombosis of the Extremities in the Home Setting

Note: This document does not address compression devices with combined cooling or heating functions intended to treat conditions other than lymphedema. For more information regarding such devices, please see:

- DME.00037 Cooling Devices and Combined Cooling/Heating Devices

Note: This document does not address gradient compression sleeves used to treat upper extremity lymphedema following breast surgery. Such sleeves are considered DME and may be subject to the WHCRA coverage mandate.

Note: The Women's Health and Cancer Rights Act of 1998 (WHCRA) is federal legislation that provides that any individual with insurance coverage who is receiving benefits in connection with a mastectomy covered by their benefit plan (whether or not for cancer) who elects breast reconstruction, must receive coverage for the reconstructive services as provided by WHCRA. This includes reconstruction of the breast on which the mastectomy has been performed, surgery and reconstruction of the other breast to produce a symmetrical appearance and prostheses and treatment of physical complications of all stages of the mastectomy including lymphedemas. If additional surgery is required for either breast for treatment of physical complications of the implant or reconstruction, surgery on the other breast to produce a symmetrical appearance is reconstructive at that point as well. The name of this law is misleading because: 1) cancer does not have to be the reason for the mastectomy; and 2) the mandate applies to men, as well as women. WHCRA does not address lumpectomies. Some states have enacted similar legislation, and some states include mandated benefits for reconstructive services after lumpectomy.

Clinical Indications

Medically Necessary:

Single or multi-chamber or segment *non-programmable* compression devices are considered **medically necessary** when the criteria below have been met:

A. Treatment of upper or lower limb lymphedema; **and**
B. The individual's lymphedema is not improving; **and**
C. The individual has been compliant with conservative therapy*

*Conservative therapy may include any combination of the following: elevation of the affected limb, exercise, massage, use of an appropriate compression bandage system or compression garment.

Single or multi-chamber or segment *programmable* (for example, calibrated gradient pressure) compression devices are considered **medically necessary** when the criteria below have been met:

A. The criteria above for a non-programmable compression device have been met: **and**
B. Criteria 1 *or* 2 below have been met:
    1. All of the below:
        a. A single or multi-chamber or segment *non-programmable* compression device has been tried for a minimum of 3 months; **and**
        b. There is documentation of compliance with treatment with the *non-programmable* pneumatic compression device; **and**
        c. The records provide objective documentation that lymphedema has progressed;

    or

    2. There is clear documentation of a condition that prevents the satisfactory treatment of lymphedema with a *non-programmable* device. Such conditions may include, but are not limited to the following:
        a. Contracture; or
        b. Sensitive skin; or
        c. Significant scarring.

Not Medically Necessary:

Single *or* multi-chamber or segment *programmable* or *non-programmable* compression devices for the treatment of upper or lower limb lymphedema are considered **not medically necessary** when the criteria above have not been met.

Two-stage* multi-chamber or segment *programmable* compression devices are considered **not medically necessary** for the treatment of upper or lower limb lymphedema.

***Note:** Two-stage devices involve an initial programmed compression of the chest and/or trunk, the "preparatory stage," followed by a second programmed compression of the affected limb(s), the "drainage" stage.

The use of compression devices to treat lymphedema in any body part other than the upper or lower extremities is considered **not medically necessary**.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS

	Single- and multi-chamber devices
E0650	Pneumatic compressor, non-segmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0655	Non-segmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Non-segmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Non-segmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Non-segmental 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 arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0681	Non-pneumatic compression controller without calibrated gradient pressure
	Programmable devices (specified as one stage)
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg
E0678	Non-pneumatic sequential compression garment, full leg
E0679	Non-pneumatic sequential compression garment, half leg
E0680	Non-pneumatic compression controller with sequential calibrated gradient pressure
E0682	Non-pneumatic sequential compression garment, full arm

ICD-10 Diagnosis

C50.011-C50.929	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast

D05.00-D05.92	Carcinoma in situ of breast
D48.60-D48.62	Neoplasm of uncertain behavior of breast
D49.3	Neoplasm of unspecified behavior of breast
I89.0	Lymphedema, not elsewhere classified
I97.2	Postmastectomy lymphedema syndrome
I97.89	Other postprocedural complications and disorders of the circulatory system, not elsewhere classified [when specified as lymphedema]
Q82.0	Hereditary lymphedema

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

When services are also Not Medically Necessary:
For the following procedure codes; or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

HCPCS	
	Programmable devices (specified as two stage) and areas other than extremities
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg
E0677	Non-pneumatic sequential compression garment, trunk
E1399	Durable medical equipment, miscellaneous [when specified as pneumatic compression garment with a pneumatic compression device]
ICD-10 Diagnosis	
C50.011-C50.929	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast
D05.00-D05.92	Carcinoma in situ of breast
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Discussion/General Information

Lymphedema is characterized by swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid resulting from impairment of the normal clearing function of the lymphatic system and/or from an excessive production of lymph. Lymphedema is divided into two broad classes according to etiology. Primary lymphedema is a relatively uncommon, chronic condition due to congenital absence of lymph vessels and nodes, and may be due to Milroy's Disease. Secondary lymphedema, which is much more common, results from the destruction or damage of formerly functioning lymphatic channels. Examples include radical surgical procedures with removal of regional groups of lymph nodes (for example, after radical mastectomy), post-radiation fibrosis, and spread of malignant tumors to regional lymph nodes with lymphatic obstruction. Treatment for lymphedema may include mechanical measures (for example, compression garments, bandaging, manual massage, compression devices), drugs, and in rare cases, surgery.

Multiple compression devices have been approved through the U.S. Food and Drug Administration's (FDA's) 510(k) process. Such devices are classified as Class II devices: cardiovascular therapeutic devices, and compressible limb sleeves. Such devices, also known as lymphedema pumps, are used to simulate muscle action in the extremities to stimulate lymph and blood circulation with the goal of decreasing edema due to accumulation of lymphatic fluid. These devices involve the use of sleeve or wrap-like garments which contain mechanisms that apply compression. The traditional type of compression devices involves the use of one or several inflatable air chambers. A more recent type of device uses metal bands that contract under electrical stimulation to create calibrated compression (Dayspring system, Koya, Inc., San Francisco, CA). During treatment, these devices apply compression in a distal to proximal fashion, squeezing the body in such a way as to encourage lymphatic fluid to flow back to the heart. Some devices come with control units that are programmable, allowing variation in the duration and frequency of the inflation cycles, as well as the degree of compression in individual air chambers or metal band segments in the garment. The ability to vary different aspects of this type of treatment has been suggested as a method of optimizing the treatment process, but there is no evidence to demonstrate the superiority of programmable devices compared to non-programmable devices.

The Women's Health and Cancer Rights Act of 1998 (WHCRA) mandated that treatment of physical complications of all stages of the mastectomy, including lymphedemas, may be covered by their benefits for individuals who have undergone surgical breast procedures. This includes the use of compression devices that involve externally applied pressure to move fluid from the distal portions of the body toward the heart.

Treatment of the Extremities

The scientific literature addressing the use of compression devices for the treatment of lymphedema has predominantly focused on the treatment of affected limbs using pneumatically driven devices.

In a systematic review published in 2012, Oremus et al. reviewed 44 studies evaluating the use of various conservative therapies for the treatment of secondary lymphedema, most of which involved upper limb

lymphedema secondary to breast cancer. They reported that the available evidence is of poor quality and that significant heterogeneity made between-study or between-therapy comparisons impossible. They concluded that there is currently no evidence to demonstrate the superiority of any one therapy for lymphedema.

Szuba and colleagues (2002) reported on two small randomized controlled trials (RCTs) (n=23 and n=27, respectively). The results of these studies showed that during initial treatment, standard therapy plus pneumatic compression for treatment-naive subjects resulted in significant limb volume reduction compared to standard care alone. However, they found that during the maintenance period, these benefits did not persist in some individuals. In contrast to these findings, earlier small randomized controlled studies by Johansson et al (1998), and Dini and colleagues (1998) found no significant difference between pneumatic pump therapy when compared to either no care or standard care groups.

Gurdal and colleagues (2013) reported the results of a RCT involving 30 subjects randomized to receive one of two different combination treatments for lymphedema. Fifteen subjects received manual lymphatic drainage (MLD) and compression bandage combination (Group 1). The remaining 15 subjects were treated with intermittent pneumatic compression (IPC) plus self-lymphatic drainage (SLD) (Group 2). Both groups received treatment for 3 days a week, every other day, for 6 weeks. Arm circumferences were measured before treatment and at 1, 3, and 6 weeks. Quality of life was measured using the EORTC-QLQ and ASES evaluation tools before and after 6 weeks of treatment. Both groups had significant decrease in total arm volume (12.2% decrease in Group 2 and 14.9% decrease in Group 1; $p<0.001$), but no significant difference was found between the two groups ($p=0.582$). Similarly, ASES scores were significantly ($p=0.001$) improved in both groups without any significant difference between the groups. The authors did note that while emotional functioning, fatigue, and pain scores were significantly improved in both groups, measures of global health status, functional and cognitive functioning scores appeared to be improved only in patients of Group 1. A similarly designed RCT was reported by Uzkeser et al. in 2013. In this study, 15 subjects were randomized to receive complex decongestive therapy (CDT) that included skin treatment, MLD, compression bandages, compression garments, and exercise (Group 1). Another group was randomized to receive CDT in addition to intermittent pneumatic compression therapy (Group 2). Both groups were treated 5 times a week for 3 weeks. Significant benefits were reported for both groups, but no differences between groups were noted. Given these recent results, large well-designed randomized controlled trials are warranted to better understand the potential impact of this therapy.

Fife and others (2012) conducted an RCT with 36 subjects randomized to receive treatment with either a standard non-programmable multi-chamber pneumatic compression device (n=18) or a programmable, multi-chamber compression device (n=18). The latter group included both extremity and partial chest/trunk therapy, while the standard group received only upper extremity therapy. Treatment in both groups was 1 hour a day for 12 weeks. The authors report that after 12 weeks the percentage edema volume, calculated as the difference between the volume in mL of the treated arm volume compared to the contralateral arm, was significantly better in the programmable therapy group (-29 ± 44% in the programmable group vs. +16 ± 63% for the non-programmable group; p=0.018). There were a total of six adverse events reported that were classified as either "possibly" or "definitely" device-related; one in the programmable group and five in the standard group. No statistics were provided for this difference. It should be noted that edema volume is used as the primary outcome metric in this

study. Data regarding lymphedema symptoms, quality of life, or functional outcomes are not presented. While this pilot study indicates some potential benefits to the use of programmable devices, the small study population, lack of blinding, and failure to measure clinically relevant outcomes limit the generalizability of this data. Evidence from larger RCTs or other comparative studies is needed to evaluate whether programmable devices should be used first line as opposed to after failure of a non-programmable device.

Desai (2019) reported on the results of a case series study involving 128 subjects with lower extremity lymphedema treated with pneumatic compression therapy. The authors report significant benefits after the completion of 1 year of treatment, including a 28% decrease in absolute limb volume ($p<0.001$), decrease in body-mass index (BMI) ($p<0.001$), improvement in SF-36 quality of life score in 7 of 8 domains ($p<0.001$), and improvement in a lymphedema complexity score (LLCS) ($p<0.001$).

Maldonado and colleagues (2020) reported the interim results of a case series study involving 178 predominantly older, obese subjects with lower limb lymphedema treated with the Flexitouch device. The report included the results of the first 74 subjects to reach the 52-week treatment endpoint. Results as measured by the Lymphedema Quality of Life (LYMQOL) tool at 52 weeks indicated significantly improved outcomes from baseline (6.3 vs. 7.4, $p<0.0001$). On the SF-36 survey tool, significant improvements from baseline were reported for the Physical Component (38.6 vs. 40.8; $p=0.035$). Additionally, measurements of limb circumference were significantly reduced at 12 weeks from baseline (28.5 cm vs. 27.7 cm; $p=0.0005$) in the most affected leg. This result persisted throughout the remainder of the study period. The authors also reported that treatment with the Flexitouch device was associated with a significant reduction in incidence of cellulitis (24.3% vs. 8.1%, $p=0.005$), lymphedema-related clinic visits (2.2 vs. 0.7; $p=0.02$), urgent care visits (1.2 vs. 0.3; $p=0.004$), and hospital admissions (0.5 vs. 0.1; $p=0.047$).

Tastaban (2020) reported the results of a non-blind RCT involving 76 subjects with cancer-related lymphedema assigned to receive either standard care (n=38) or standard care plus pneumatic compression therapy (n=38). The authors reported significant improvements in both groups with regard to limb volume reduction, and limb heaviness and tightness, but no differences between groups.

Maldonado (2021) reported the interim results of a prospective case series study involving 178 subjects with lower limb lymphedema being treated with the Flexitouch Advanced pneumatic compression device (APCD). The report includes data from the first 74 subjects to reach the 52-week study endpoint. LYMQOL results demonstrated significant improvement from baseline at 52 weeks (6.3 points vs. 7.4 points, $p<0.0001$). Additionally, limb circumference decreased significantly during the same timeframe (28.5 cm vs. 227.7 cm, $p<0.0005$). This finding was durable throughout the study period. Finally, the authors reported reduction in the number of episodes per participant of the following: cellulitis (24.3% vs. 8.1%, $p=0.005$), lymphedema-related clinic visits (2.2 vs. 0.7, $p=0.02$), urgent care visits (1.2 vs. 0.3, $p=0.004$), and hospital admissions (0.5 vs. 0.1, $p=0.047$). These results are supportive of compression therapy, but results of the full cohort will provide better data.

Rockson (2022a) and colleagues reported the results of a prospective, non-randomized controlled study involving 40 subjects with unilateral upper extremity lymphedema. The lymphedematous arm was treated with the Koya

Dayspring system and the contralateral arm was used as a control group. Treatment was applied for a minimum of 45 minutes a day, every day, for 28 days. The authors reported that overall LYMQOL results improved 18% (7.05 points at baseline to 8.27 points at 28 days, p<0.001). Similar improvements were reported in a subset of 15 subjects who had previously received treatment with pneumatic compression device therapy (17%, 7.07 point to 8.27 points at 28 days, p<0.001). Limb volume reduction in the treated arm was reported on average of 2% by the end of the study period at 28 days (p~0.042), compared to no significant change in the control arms. Previously treated subjects also had significant improvements in limb volume (2-12%, p<0.05). Adherence to protocol was 95%, as measured by mobile application linked to the Dayspring device.

Rockson (2022b) also published the results of an unblinded non-inferiority RCT involving 50 subjects with breast-cancer-related upper limb lymphedema. Subjects were treated with either the Dayspring device or a standard advanced pneumatic compression device (control group) for 28 days, then underwent a 4-week washout period with no compression device use, followed by a second 28-day treatment period with the alternative device. The Dayspring device was used first for 23 subjects and the control device was used in the remaining 27 subjects. The mean reduction in edema volume was reported to be 64.6% in the Dayspring device group and 27.7% in the control group which the authors concluded met the primary endpoint of non-inferiority. LYMQOL scores in the Dayspring group indicated a 2.44 point increase compared to no change in the control group. The difference in improvement for the Dayspring group was statistically significant (p<0.05). However, these results should be viewed in light of a significant difference in use compliance between groups, with 95.6% of Dayspring subjects complying with the 60-minute per day therapy and only 49.8% of the control group subjects complying. No serious adverse events were reported for either device, with no new hand or chest swelling observed in either group.

Dunn (2022) reported on an RCT involving 40 subjects with lower limb lymphedema treated with pneumatic compression using the LymphAssist intermittent pneumatic compression regimen or a sequential compression therapy regimen. Treatments used 40 mmHg of pressure for 35 minutes twice daily for five weeks. A total of 33 subjects had bilateral lower limb disease and 7 had unilateral disease. All subjects were blinded to group assignment group. The authors reported that the LymphAssist group had significantly reduced distal leg volume when compared to the control sequential compression group (reduction of 230–135mL vs. 140–84 mL, respectively, p=0.01). No differences in proximal leg volume were reported (reduction of 124–118mL vs. 150–158mL, respectively, p=0.7).

Overall, the available evidence, although weak, indicates significant benefits to upper and lower extremity compression therapy with standard or “advanced” devices. While these benefits do not appear to be better than manual decompressive treatment, the evidence to date appears to point to equivalence. On the basis of this data the use of compression therapy has become widely recognized in the practicing community as a reasonable option and part of the standard of care for the treatment of upper and lower limb lymphedema.

Treatment of the Head and Neck.

There are few studies available describing the use of compression devices for the treatment of head and neck lymphedema. A small case series study involving 44 subjects and reported on the usability and treatment-related

lymphedema changes following a single treatment (Mayrovitz, 2018). The authors reported a small but statistically significant reduction in composite metrics of the face (82.5 ± 4.3 cm vs 80.9 ± 4.1 cm; p<0.001) and neck (120.4 ± 12.2 cm vs 119.2 ± 12.1 cm; p<0.001), with no adverse events. The results of this study are limited due to the weak methodology and low power.

Gutiérrez (2020) reported on the results of a case series study involving 499 subjects with head and neck lymphedema treated with the Flexitouch device. A total of 205 subjects had complete data and were included in the report. The authors reported that the results of self-reported questionnaires demonstrated, when compared to baseline, a significant increase in the ability to control lymphedema symptoms through at-home treatment (1.89 ± 0.96 vs. 3.61 ± 0.96; p<0.00001), a decrease in the frequency of lymphedema-related limitations to perform daily activities (3.22 ± 1.38 vs. 4.01 ± 1.17; p<0.00001), improvement in head and neck pain or discomfort (3.13 ± 1.16 vs. 3.61 ± 1.03; p<0.00001), decreased difficulty with swallowing (2.90 ± 1.28 vs. 3.57 ± 1.21; p<0.00001), and improved ability to breathe (3.94 ± 1.13 vs. 4.44 ± 0.88; p<0.00001). The results of this study are promising, but generalizability is limited by the weak methodology, large loss to follow-up, subjective outcomes reported and lack of objective measures.

Ridner (2020) reported on a non-blind RCT involving 49 subjects with head and neck lymphedema treated with standard care (n=25) or the Flexitouch device (n=24). Six subjects withdrew from the study before completion, 1 in the control group and 5 in the Flexitouch group leaving 24 control subjects and 19 Flexitouch subjects. Most Flexitouch subjects (< 50%) did not follow the prescribed treatment schedule of 2 treatments per day, and only used it once per day. Flexitouch group subjects reported an increase in perceived ability to control lymphedema (26% good or excellent at baseline vs. 84% good or excellent at 8 weeks, p=0.003). Statistically significant reductions in the reported severity of soft tissue (p=0.008) and neurological (p=0.047) symptom clusters were reported in the Flexitouch group vs. controls, based on the Lymphedema Symptom Intensity and Distress Survey-Head and Neck (LSIDS-HN) tool. A statistically significant improvement in swallowing solids (p=0.016) and mucous-related symptoms (p=0.050) was reported for the Flexitouch group vs. controls as measured on the Vanderbilt Head and Neck Symptom Survey plus General Symptom Survey version 2.0 (VHNSS-GSS). Furthermore, control subjects reported an increase in general pain vs. Flexitouch group subjects who reported the same level as at baseline (p=0.008). Based on photographic analysis, the degree of visible external swelling was significantly better in the Flexitouch group (front view p<0.001, right view p=0.004, left view p=0.005). Differences in internal swelling via endoscopic evaluation were not statistically significant between groups. These results indicate some significant benefits, but are hampered by loss to follow-up, low power, lack of blinding, and other methodological flaws.

While these results are promising, additional larger, well-designed, and conducted long-term studies are needed to establish the role of pneumatic compression therapy for head and neck lymphedema in standard treatment regimens.

Two-Stage Devices

Multi-chamber or segment programmable pneumatic compression devices may also function with two-phases. The first phase, referred to as the "preparatory phase," compresses the trunk (chest/abdomen). The preparatory phase is

designed to prepare the limb for a secondary (drainage) compression phase. The combination of these two phases (preparation plus drainage) has been proposed as a method to further enhance lymph drainage.

A device currently available and marketed by Tactile Medical® (Minneapolis, MN), the Flexitouch Plus® system, may include compression garments for treatment of the head and neck, upper body (chest), lower torso (trunk), upper extremities, and lower extremities. When the lower extremity garment is used alone the system is a single-stage device.

The available evidence addressing the clinical use of two-stage multi-chamber or segment programmable pneumatic compression devices is limited. In addition to several case reports published in journals not recognized in the National Library of Medicine's PubMed database (Cannon, 2009; Hammond, 2009a, 2009b), there are a few case series and a limited number of RCTs available. The Ridner (2008) case series initially included 286 participants who underwent treatment with a two-stage compression device for 2 months. Prior to treatment, and 2 months following the initiation of treatment, the subjects were asked to respond to a survey instrument regarding Quality of Life (QOL) and satisfaction with the device. In addition to methodological flaws such as the use of self-reported data, lack of a control group, no blinding and a significant loss to follow-up (36%), the study does not report health-related outcomes, such as limb volume reduction, skin tension and elasticity, and limb heaviness.

Muluk and colleagues published the results of a prospective case series study involving 196 subjects with lower extremity lymphedema (2013). The majority (181 of 196) of subjects were treated with a two-stage treatment regimen. A total of 88% (n=173) of the subjects experienced a significant reduction in limb volume with 35% reporting a reduction greater than 10%. Mean limb volume reduction was 1,150 mL or 8% ($p<0.0001$). Clinician assessment indicated that the majority of participants experienced improvement in skin fibrosis (86%, n=168) and function (77%, n=149). However, it is not clear what tools were used to make these assessments.

A randomized controlled, cross-over trial which included 10 subjects with unilateral breast cancer-associated lymphedema of the arm compared treatment with a two-stage device vs. self-administered massage (Wilburn, 2006). The authors reported significant improvement in limb volume, mean subject weight, but no significant differences in SF-26 quality of life scores. There was no comparison to conventional single-stage pump therapy in this very small study with a limited follow-up period of only 4 weeks.

A small RCT of two-stage compression therapy has been published. Ridner and colleagues (2012) studied 42 subjects randomized to receive either upper extremity-only compression treatment (control group; n=21) or extremity plus chest and trunk compression treatment (two-stage therapy) (experimental group; n=21). Control subjects underwent 30 treatments of 36 minutes each. The experimental group received 30 treatments of 1 hour each. The first treatment was supervised in the office, but all subsequent sessions were unsupervised in the home. The authors reported significant improvements with regard to function and anatomical measures in both groups, but no significant differences between groups.

In 2017, Karaca-Mandic and colleagues published the results of a retrospective analysis of administrative claims from 1731 subjects with cancer (n=621) and non-cancer-related (n=1110) lymphedema who were treated with

either a segmented non-programmable pneumatic compression device (n=1013) or the Flexitouch™ device (n=718). Further stratification for the subjects with cancer-related lymphedema resulted in 247 subjects treated with the non-programmable pump and 374 treated with the Flexitouch device. For the non-cancer subjects, there were 766 subjects treated with the non-programmable pump and 344 in the Flexitouch group. Data are presented for the first 12 months of therapy. At baseline, the non-programmable group had a high proportion of obesity, diabetes, hypertension, and renal disease (p<0.001 for all). The Flexitouch group had a significantly higher proportion of breast cancer vs the non-programmable group (76% vs. 43%, p=<0.001). In the cancer group, the Flexitouch group had a higher rate of improvement in cellulitis vs the non-programmable group (79% reduction vs. 53%, p=0.02). The rate of outpatient services was significantly better in the Flexitouch group vs. the non-programmable group (reduction of 1.84 vs. 0.31, p=0.001). The rate of hospitalizations was not significantly different between groups, and use of manual therapy declined a similar amount for each group, with no significant differences. In the non-cancer group, the Flexitouch group had a higher rate of improvement in cellulitis vs the non-programmable group (76% reduction vs. 54%, p=0.003). The use of manual therapy declined at a greater rate in the Flexitouch group vs. the non-programmable group (p=0.04). The rate of outpatient services was significantly better in the Flexitouch group vs. the non-programmable group (reduction of -22.8% vs. -7.8%, p<0.001). The rate of hospitalizations did not change in non-programmable group, whereas it did improve significantly in the Flexitouch group (6/6% to 2/9%, p=0.03). Overall the authors noted that outpatient service use was reduced in both device groups, with greater reductions observed in Flexitouch group. Also, both device groups experienced reductions in manual therapy use. Inpatient hospitalizations were largely stable with reductions observed only in the non-cancer cohort of the Flexitouch group. They conclude that use of the Flexitouch device "was associated with superior lymphedema-related health outcomes and reductions in cellulitis." It must be noted that this study included claims from 2007 through 2013. During that period, two-stage Flexitouch devices were in use. While it can be assumed that the data was derived with the use of two-stage devices, no data is provided in the publication to determine whether or not the devices involved in treatment were two-stage or not. Thus, it is not clear whether or not the results, in part or in their entirety, can be attributed to the use of two-stage devices.

In summary, the available evidence regarding two-stage devices published in the peer-reviewed medical literature does not demonstrate that the use of two-stage devices improves the net health outcome or is as beneficial as established alternative, such as single-stage (non-programmable or programmable) treatment of lymphedema.

Lymphedema Related to Massive Obesity

There is some low-level evidence that massive obesity may rarely be a cause of massive localized lymphedema (MLL), a condition affecting the pelvic region and lower extremities (Chopra, 2015; Mehrara, 2014). Several case reports and small case series studies have been published characterizing MLL (Fife, 2008, 2014; Greene, 2013, 2015a).

In the only report of its kind, Greene (2015b) published the results of a case series study involving 51 subjects with Body Mass Index (BMI) greater than 30 kg/m^2 and lymphedema with no other potential causes of the condition. All subjects underwent lymphoscintigraphy to assess lower extremity lymphatic function. The authors reported that subjects with abnormal lymphoscintigraphy results had higher BMI vs. subjects with normal results (mean 64.9

kg/m^2 vs. 38.8 kg/m^2; p<0.0001). Subjects were stratified into two groups. Group 1 subjects were at their maximum BMI (n=33), while group 2 subjects had experienced some weight loss at the time of lymphoscintigraphy (n=18). All subjects in group 1 with a BMI less than 50 kg/m^2 (n=20) had normal lymphoscintigraphy results. In the same group, all subjects with a BMI greater than 60 kg/m^2 (n=9) had abnormal results. In group 2, subjects with abnormal lymphoscintigraphy results had higher maximum BMI history (p=0.03) as well as higher BMI at the time of the scan (p=0.005) compared to subjects in group 1 with normal results. These results appear to indicate that MLL is directly correlated with higher BMI, specifically BMI over 50 kg/m^2.

The treatment of MLL can be a significant challenge due to the large size and location of the lymphedema. The preferred method of treatment is currently surgical excision, especially when ulcers or infections are present. However, there is some anecdotal evidence that such lesions may return, and with greater severity than the initial lesion (Fife, 2014). Additionally, there is some evidence that massive weight loss does not reverse the presence of MLL (Greene, 2015a, 2015b). Given the difficulty in treating MLL, conservative therapy of the lower extremities with pneumatic compression therapy may be reasonable. The use of pneumatic compression therapy for MLL related truncal lymphedema has not been demonstrated to provide any significant benefit.

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Index

LymphFlow Advance
LymphaPress Optimal™
NormaTec PCD

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
	01/04/2024	Revised Discussion/General Information section text regarding two-stage devices.
Revised	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised formatting in Clinical Indications section. Revised Discussion/General Information and References sections. Updated Coding section with 01/01/2024 HCPCS changes, added HCPCS codes E0681, E0678, E0679, E0680, E0682 replacing K1024, K1025, K1031, K1032, K1033 eff 01/01/2024.
	03/29/2023	Updated Coding section with 04/01/2023 HCPCS changes; added E0677.
Revised	11/10/2022	MPTAC review. Revised note text in MN statement. Updated Description, Discussion, References, and Index sections.
	04/01/2022	Updated Coding section with 04/01/2022 HCPCS changes; added K1031, K1032, K1033.
Revised	11/11/2021	MPTAC review. Revised title to remove "Pneumatic". Expanded scope to include non-pneumatic devices. Updated formatting of Position Statement section. Revised Position Statement text regarding the use of "pneumatic". Clarified NMN section. Updated Discussion, References, and Index sections. Updated Coding section; added codes K1024, K1025.
Revised	02/11/2021	MPTAC review. Clarified location of lymphedema in Clinical Indications Section. Updated Discussion, References, and Index sections. Reformatted Coding section.
Reviewed	02/20/2020	MPTAC review. Updated Description, Discussion, and References sections.
Reviewed	03/21/2019	MPTAC review. Updated Description, Discussion, and References sections.
	11/15/2018	Added note to Description section clarifying that gradient compression stockings/sleeves for post breast surgery upper extremity lymphedema are not addressed in this document.
Revised	03/22/2018	MPTAC review. Added head and neck pneumatic compression to the NMN statement. Updated Description, Discussion and References sections. Updating coding section to include HCPCS E1399.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Discussion and References sections.

Reviewed	11/03/2016	MPTAC review. Updated formatting in Clinical Indications section. Updated Reference section.
Revised	11/05/2015	MPTAC review. Added clarification to medically necessary section regarding the use of multi-chamber programmable pumps. Updated Discussion/General Information and References sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. No change to clinical indications. Updated References section.
Revised	11/14/2013	MPTAC review. Added new criteria for programmable pump use. Added note in not medically necessary statement addressing use of two-stage devices. Updated Rationale and References sections.
Revised	11/08/2012	MPTAC review. Added not medically necessary statement to address the use of pneumatic compression devices for the trunk and chest. Updated Discussion and References sections. Updated Coding section with 01/01/2013 HCPCS changes.
Revised	08/09/2012	MPTAC review. Deleted position statement addressing venous insufficiency, Updated Discussion, Coding, References, and Index sections.
	05/22/2012	Updated title to add "for Lymphedema" and added note to Description section to clarify scope of document.
Reviewed	08/18/2011	MPTAC review. No change to position statement. Updated Coding and References sections.
Reviewed	08/19/2010	MPTAC review. No change to position statement. Updated Discussion and References sections.
Reviewed	08/27/2009	MPTAC review. No change to position statement. Added LymphaPress Optimal, NormaTec PCD devices to document. Updated Discussion and References sections.
	01/01/2009	Updated coding section with 01/01/2009 HCPCS changes.
Revised	08/28/2008	MPTAC review. Clarified not medically necessary statement. Revised Discussion section.
Revised	08/23/2007	MPTAC review. Added not medically necessary statement for single or multi-compartment programmable or non-programmable pneumatic compression devices when medically necessary criteria have not been met; updated Reference section.
Reviewed	09/14/2006	MPTAC review. No change to position; updated reference section.
	11/21/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	09/22/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.		None	None

Anthem BCBS	07/10/2002	Memo 115	Lymphedema Pumps
Anthem BCBS	10/29/2004	DME.218	Pneumatic Compression Devices
WellPoint Health Networks, Inc.	06/24/2004	9.01.05	Lymphedema Pumps