Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

Children's Medical Services Health Plan (CMS Health Plan)

Staywell of Florida

WellCare (Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maine, Michigan, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, South Carolina, Tennessee, Texas, Washington)

WellCare Prescription Drug Plans (PDP)

WellCare Heritage Health

WellCare TexanPlus (Medicare – Dallas & Houston markets)

Treatment for Peripheral Lymphedema (including Pneumatic Compression Devices)

Policy Number: HS-078

Original Effective Date: 2/2/2009

Revised Date(s): 2/26/2010; 2/26/2011; 2/2/2012; 2/7/2013; 2/6/2014; 2/5/2015; 2/4/2016, 2/2/2017; 2/1/2018; 2/7/2019; 3/10/2020

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Lymphedema is an accumulation of lymphatic fluid in the interstitial tissue, principally in the subcutaneous fatty issues. The condition is marked by an abnormal collection of excess tissue proteins, edema, chronic inflammation, and fibrosis. Fluid accumulation results in gradual and progressive enlargement of the affected extremity or other region of the body accompanied with declines in functional and immunological capabilities, increased weight, and morphological changes. Lymphedema is a frequent complication of cancer and its treatments, and the condition can have long-term physical and psychological consequences. It is typically a progressive and debilitating condition with no known cure. The reported incidence of lymphedema varies due to discrepancies in its definition and classification, measurement of affected areas, and other factors. In the United States, the highest incidence of lymphedema is

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observed among patients who undergo breast cancer surgery, particularly among those who undergo radiation therapy following axillary lymphadenectomy. Among this patient population, estimates of lymphedema frequency range from 10% to 40%. Estimates of worldwide lymphedema cases range from 120 to 250 million, with lymphedema filariasis being the most common type.

Pneumatic compression devices are commonly used for the treatment of acute and chronic peripheral lymphedema to facilitate the mobilization of fluid from the limbs into the trunk and central body cavity. These devices have also been used in the treatment of venous stasis, venous and arterial ulcers, and for the prevention of deep vein thrombosis. Pneumatic compression devices generally consist of an inflatable garment for the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary among devices. Designed for use in both the home and institutional settings, the devices are generally intended to assist patients suffering from peripheral and vascular disorders, including primary or secondary lymphedema. The devices are currently used in both the primary and adjunctive treatment of lymphedema (from Hayes, 2005).

Microsurgical Treatment for Lymphedema

Two main types of microsurgery exist and the goal of each is to promote lymphatic drainage and to reduce swelling. In one, lymph vessels are directly connected to veins (derivative techniques). In the other, blocked or missing lymph vessels are replaced by grafts taken from the patient's own blood or lymph vessels and/or by transplanting a lymph node(s) from other areas of the body such as the groin (reconstructive techniques). In all cases the operation is carried out using surgical microscopes and miniature specialized instruments and sutures. Such operations are lengthy and technically difficult, and are usually performed by plastic surgeons, or other surgeons with relevant expertise in microsurgery. Patients often require complex and detailed imaging procedures prior to surgery. Surgery is performed on inpatients who receive general anesthesia.

There is some evidence, some of which is long-term, from three small case series and one comparative trial that lymphaticovenous microsurgery can reduce swelling and arm circumference and improve quality of life in breast cancer patients with postmastectomy lymphedema who do not respond to standard compression and manual drainage. However, these studies employed a variety of microsurgical procedures, and interpretation of the data is complicated by the concomitant use of compression therapy in some cases. The sample sizes are small, and there are no well-designed controlled trials employing this therapy. Therefore, despite the apparent promising findings among the few patients reported on thus far, definitive conclusions regarding the efficacy and safety of this therapy cannot be reached at this time (from Hayes, 2007).

Chronic Venous Insufficiency with Venous Stasis Ulcers

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

General Coverage Criteria from Centers for Medicare and Medicaid Services

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

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

The only time that a segmented, calibrated gradient pneumatic compression device would be covered is when the

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individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber.

POSITION STATEMENT

Applicable To:

- ☑ Medicaid (excluding KY)
- ☑ Children's Medical Services Health Plan (CHIP)
- ☑ Medicare

Exclusions

The following lymphedema treatments are **not considered medically necessary and not a covered benefit:**

1. Lymphedema compression sleeves are not medically necessary for the treatment of lymphedema.
2. Two-phase lymph preparation and drainage therapy devices (e.g., Flexitouch® Lymphedema System) are considered experimental and investigational and NOT a covered benefit.
3. Microsurgical lymphaticovenous anastomosis is considered experimental and investigational and NOT a covered benefit. The long-term effectiveness of this procedure has not been established in the scientific literature.

Coverage

Lymphedema Treatment

Pneumatic compression devices (lymphedema pumps) **are considered medically necessary** for the treatment of lymphedema when ALL of the following criteria are met:

1. Member has experienced failure of a four-week trial of conservative medical management including ALL of the following:
   A. Home exercise program; **AND,**
   B. Limb elevation; **AND,**
   C. Compression bandage or compression garment use

Chronic Venous Insufficiency Treatment

Pneumatic compression devices **are considered medically necessary** for the treatment of chronic venous insufficiency with venous stasis ulcers if ALL of the following criteria are met:

1. The member has one or more venous stasis ulcers; **AND,**
2. Ulcers have failed to heal after a six month trial of conservative therapy including **ALL** of the following:
   A. Use of a compression bandage system or compression garment; **AND,**
   B. Appropriate dressings for the wound; **AND,**
   C. Exercise; **AND,**
   D. Elevation of the limb.

CODING

Covered CPT®* Codes

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

HCPCS© Codes

A6530 Gradient compression stocking, below knee, 18-30 mm Hg, each
A6531 Gradient compression stocking, below knee, 30-40 mm Hg, each

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A6532 Gradient compression stocking, below knee, 40-50 mm Hg, each
A6533 Gradient compression stocking, thigh length, 18-30 mm Hg, each
A6534 Gradient compression stocking, thigh length, 30-40 mm Hg, each
A6535 Gradient compression stocking, thigh length, 40-50 mm Hg, each
A6536 Gradient compression stocking, full length/chap style, 18-30 mm Hg, each
A6537 Gradient compression stocking, full length/chap style, 30-40 mm Hg, each
A6538 Gradient compression stocking, full length/chap style, 40-50 mm Hg, each
A6539 Gradient compression stocking, waist length, 18-30 mm Hg, each
A6540 Gradient compression stocking, waist length, 30-40 mm Hg, each
A6541 Gradient compression stocking, waist length, 40-50 mm Hg, each
A6544 Gradient compression stocking, garter belt
A6345 Gradient compression wrap, nonelastic, below knee, 30-50 mm Hg, each
A6549 Gradient compression stocking, not otherwise classified
E0650 Pneumatic compressor, nonsegmental home model
E0651 Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652 Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655 Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0660 Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665 Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666 Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667 Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668 Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669 Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0670 Segmental pneumatic appliance for use with pneumatic compressor, intergrated, 2 full legs and trunk
E0671 Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0672 Segmental gradient pressure pneumatic appliance, full arm
E0673 Segmental gradient pressure pneumatic appliance, half leg
S8420* Gradient pressure aid (sleeve and glove combination), custom made
S8421* Gradient pressure aid (sleeve and glove combination), ready made
S8422* Gradient pressure aid (sleeve), custom made, medium weight
S8423* Gradient pressure aid (sleeve), custom made, heavy weight
S8424* Gradient pressure aid (sleeve), ready made
S8425* Gradient pressure aid (glove), custom made, medium weight
S8426* Gradient pressure aid (glove), custom made, heavy weight
S8427* Gradient pressure aid (glove), ready made
S8428* Gradient pressure aid (gauntlet), ready made
S8429* Gradient pressure exterior wrap
S8430* Padding for compression bandage, roll
S8431* Compression bandage, roll
S8950* Complex lymphedema therapy, each 15 minutes

***S- Codes are NON COVERED FOR MEDICARE – Refer to HCPCS Level II Temporary National Codes**

Covered ICD-10-CM Diagnosis Codes

I87.2 Venous insufficiency (chronic)(peripheral)
I89.0 Lymphedema, not elsewhere classified
I97.2 Post mastectomy lymphedema syndrome
I97.89 Other postprocedural complications & disorders of the circulatory system, not elsewhere classified
Q82.0 Hereditary lymphedema

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. National coverage determination for pneumatic compression devices (280.6). Centers for Medicare and Medicaid Services Web site.

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2. Flexitouch® system (Tactile Systems Technology Inc.) for lymphedema. Hayes Directory Web site. http://www.hayesinc.com. Published June 30, 2017 (annual review November 26, 2019) Accessed February 10, 2020.
3. Microsurgical treatment of lymphedema following breast cancer surgery. Hayes Directory Web site. http://www.hayesinc.com. Published July 18, 2013 (archived on August 18, 2016). Accessed February 10, 2020.
4. Pneumatic compression devices for treatment of peripheral lymphedema. Hayes Directory Web site. http://www.hayesinc.com. Published June 6, 2005 (archived on January 9, 2009). Accessed February 10, 2020.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
3/10/2020, 2/7/2019, 2/1/2018, 2/2/2017, 2/4/2016, 2/5/2015, 2/6/2014, 2/7/2013, 2/2/2012	• Approved by MPC. No changes.
12/1/2011	• New template design approved by MPC.
2/26/2011	• Approved by MPC.