Pneumatic Compression Devices (for Ohio Only)

Policy Number: CS097OH.A
Effective Date: February 1, 2024

Instructions for Use

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Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Ohio Only)

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Note: For general coverage and payment policies for durable medical equipment (DME), prosthesis, orthotic devices, medical/surgical supplies, and supplier services, refer to the Ohio Administrative Code, Rule 5160-10-01, Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions.

For medical necessity clinical coverage criteria of pneumatic compression devices for the extremities, chest, or trunk, refer to the Ohio Administrative Code, Rule 5160-10-17, DMEPOS: pneumatic compression devices and accessories.

Advanced intermittent pneumatic compression devices (e.g., Flexitouch) for treating lymphedema of the head, face, or neck are considered unproven and not medically necessary.

Intermittent limb compression devices are proven and medically necessary in an outpatient setting or upon discharge from an inpatient setting for the prevention of deep venous thrombosis (DVT). For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Pneumatic and other Powered Compression Devices.

Click here to view the InterQual® criteria.

Coverage Limitations and Exclusions

For coverage limitations and exclusions, refer to the Ohio Administrative Code, Rule 5160-10-01, Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions and the Ohio Administrative Code, Rule 5160-10-02, DMEPOS: repair.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
A4600	Sleeve for intermittent limb compression device, replacement only, each
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, integrated, two 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
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified

Clinical Evidence

Lymphedema of the Head, Face, or Neck

There is insufficient evidence in the peer-reviewed medical literature to establish the efficacy, clinical value, or safety of advanced pneumatic compression devices for treating lymphedema of the head, face or neck. Additional research is needed to define the role of advanced pneumatic compression devices in treating lymphedema of the head, face, or neck.

Gutierrez et al.(2020), in an observational study, evaluated head and neck cancer (HNC) survivors experience with head and neck lymphedema (HNL) treatment. The authors explored the self-reported outcomes and satisfaction of patients with HNC receiving treatment for HNL with an advanced pneumatic compression device (APCD). The study population included 205 patients with HNC-related HNL. Patients were predominantly male (152, 74%) with a mean age of 60 (range 13-83), the majority having squamous cell carcinoma. Participants were prescribed with an at-home Flexitouch head and neck APCD completed pretreatment and posttreatment self-reported assessments addressing efficacy, function, and symptoms. Pre-post responses for ≥ 25 days of use were assessed via the non-parametric Wilcoxon Signed Rank test. Analysis revealed statistically significant improvement in all symptoms and all function items ($p < 0.00001$). Compliance with prescribed therapy (at least 30 minutes daily) was high with 71% of participants reporting daily use and 87% reporting overall satisfaction. Despite the number of participants included, study limitations included lack of a control group which does not allow for conclusions on efficacy. The authors note that the reported improvements in function and symptoms, and high compliance rate, provide a rationale for a subsequent randomized controlled trial.

Ridner et al.(2021) conducted an open-label, multi-site, stratified randomized, wait list control, pilot study to evaluate the feasibility and efficacy regarding the use of the Flexitouch (FT) or advanced compression device (APCD) in survivors of head and neck cancer (HNC) with lymphedema. Eligible patients had completed treatment for HNC, were disease free, and had lymphedema at enrollment. Participants were randomized to wait-list lymphedema self-management (standard of care) or lymphedema self-management plus the use of the Flexitouch bid. Safety and feasibility were primary endpoints; secondary endpoints included efficacy measure by objective examination and patient reported outcomes (symptoms, quality of life, function), adherence barriers, and satisfaction. Assessments were conducted at baseline and weeks 4 and 8. Forty-nine patients were enrolled (wait-list n = 25; intervention n = 24). In total, forty-three patients completed the study. No device-related serious adverse events were reported. Most patients used the APCD once per day, instead of the prescribed twice per day, mentioning time related factors as barriers to use. APCD use was associated with significant improvement in perceived ability to control lymphedema ($p = 0.003$) and visible external swelling (front view $p < 0.001$, right view $p = 0.004$, left $p = 0.005$), as well as less reported pain. Feasibility, adherence, and safety of the Flexitouch were the primary outcomes, with efficacy included to generate initial estimates of effect for larger future trials. Given the involvedness and clinical impact of head and neck lymphedema, the feasibility of a more aggressive, twice daily treatment regimen was tested. The adherence to the twice daily regimen was low. This result is expected as patients who were compliant with twice daily treatments had available time to spend up to 1.5 h daily using their device. Time limitations were mostly due to non-adherence. On the other hand, the data demonstrated that a once daily regimen was reasonable. Therefore, future studies should investigate a once daily treatment regimen. This study also noted a decrease in lymphedema symptoms, future studies should explore the underlying mechanism related to this improvement. The authors note that this trial supports the safety and feasibility of the APCD for the treatment of secondary lymphedema in head and neck cancer patients. In addition, initial data supports efficacy. Additional research with larger RCTs is needed to confirm these findings. In particular, the sample size may have been too small to detect important but infrequent adverse events.

Maryovitz et al. (2018) conducted a case series to assess the functional usage of an advanced pneumatic compression device (Flexitouch System) for the treatment of cancer-related head and neck lymphedema as well as identifying potential clinical benefits. The primary purposes of this prospective, functional feasibility study were to assess the ease of application, garment fit and comfort, and treatment comfort of an advanced pneumatic compression system specifically designed to treat patients with head and neck lymphedema. Secondary purposes were to assess safety and acute edema changes after a single treatment. Patient-reported comfort and other treatment aspects were evaluated, and multiple face and neck measurements were obtained on 44 patients with head and neck lymphedema before and after 1 treatment session to assess usability and treatment-related lymphedema changes. The majority of patients (82%) reported the treatment was comfortable; most patients (61%) reported feeling better after treatment, and 93% reported that they would be likely to use this therapy at home. One treatment produced overall small but highly statistically significant reductions in composite metrics (mean ±SD) of the face (82.5 ±4.3 cm vs. 80.9 ±4.1 cm; $p < .001$) and neck (120.4 ±12.2 cm vs. 119.2 ±12.1 cm; $p < .001$) with no adverse events. The authors indicated that results found the treatment to be safe, easy to use, and well tolerated while demonstrating edema reduction after a single initial treatment. Larger more robust studies are needed to validate these preliminary findings, as his study was limited by short follow-up and lack of comparison group.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The Flexitouch Plus System (Tactile Systems Technology, Inc) received FDA clearance on December 20, 2020. The Flexitouch System and garments for the head and neck are intended for use by medical professionals and patients who are under medical supervision for the treatment of head and neck lymphedema. https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203178.pdf. (Accessed November 8, 2022)

Devices and systems to perform pneumatic compression are regulated by the FDA as Class II devices. Refer to the following website for more information (use product code JOW): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 4, 2019)

References

Gutiérrez C, Mayrovitz HN, Naqvi SHS, Karni RJ. Longitudinal effects of a novel advanced pneumatic compression device on patient-reported outcomes in the management of cancer-related head and neck lymphedema: A preliminary report. Head Neck. 2020 Aug;42(8):1791-1799.

Mayrovitz HN, Ryan S, Hartman JM. Usability of advanced pneumatic compression to treat cancer-related head and neck lymphedema: A feasibility study. Head Neck. 2018 Jan;40(1):137-143.

Ohio Administrative Code/5160/Chapter 5160-1-01. Medicaid medical necessity: definitions and principles. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-1-01. Accessed September 8, 2023.

Ohio Administrative Code/5160/Chapter 5160-10-01. Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-10-02. Accessed September 8, 2023.

Policy History/Revision Information

Date	Summary of Changes

02/01/2024	**Application**
	• Added language to indicate any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using *Ohio Administrative Code 5160-1-01*
	Coverage Rationale
	• Revised language to indicate:
	  ○ For general coverage and payment policies for durable medical equipment (DME), prosthesis, orthotic devices, medical/surgical supplies, and supplier services refer to *Ohio Administrative Code, Rule 5160-10-01, Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions*
	  ○ For medical necessity clinical coverage criteria of pneumatic compression devices for the extremities, chest, or trunk, refer to the *Ohio Administrative Code, Rule 5160-10-17, DMEPOS: pneumatic compression devices and accessories*
	  ○ Advanced intermittent pneumatic compression devices (e.g., Flexitouch) for treating lymphedema of the head, face or neck are considered unproven and not medically necessary
	  ○ Intermittent limb compression devices are proven and medically necessary in an outpatient setting or upon discharge from an inpatient setting for the prevention of deep venous thrombosis (DVT); for medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Pneumatic and other Powered Compression Devices
	  ○ For coverage limitations and exclusions, refer to the *Ohio Administrative Code, Rule 5160-10-01, Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions* and the *Ohio Administrative Code, Rule 5160-10-02, DMEPOS: repair*
	Supporting Information
	• Added *Clinical Evidence* section
	• Updated *FDA* and *References* sections to reflect the most current information
	• Archived previous policy version CS097OH.K – P

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]), or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC), or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC), or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC), or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.