Flexitouch® pneumatic compression devices for lymphedema after head and neck surgery

Clinical Policy ID: CCP.1448

Recent review date: 9/2025

Next review date: 1/2027

Policy contains: Flexitouch; head and neck cancer; lymphedema; pneumatic compression devices.

AmeriHealth Caritas Ohio has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Ohio'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, on a case by case basis, by AmeriHealth Caritas Ohio 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. AmeriHealth Caritas Ohio'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. AmeriHealth Caritas Ohio's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Ohio will update its clinical policies as necessary. AmeriHealth Caritas Ohio's clinical policies are not guarantees of payment.

Coverage policy

Flexitouch® pneumatic compression devices (Tactile Systems Technology, Inc., Northbrook, Illinois) for lymphedema after head and neck surgery are experimental/investigational and not clinically proven.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Complete decongestive therapy.

Background

Head and neck cancers are predominately squamous cell carcinomas and account for about 4% of all cancers in the United States. The majority of these cancers occur in men and in persons over the age of 50. Head and neck cancers can form in the oral cavity, pharynx, larynx, paranasal sinuses and nasal cavity, and salivary glands. While treatments can vary by cancer location, cancer stage, patient age, and general health, they may include chemotherapy, radiation therapy, surgery, and targeted chemotherapy (National Cancer Institute, 2021).

Lymphedema is common in up to 75% of patients who have been treated for head and neck cancer, especially from surgery and radiation. Secondary lymphedema from head and neck cancer treatment affects the face, mouth, and neck, both internally and externally. It may manifest as limitations to communication (speaking, reading, writing, and hearing), alimentation, and respiration. In severe cases, vision may be impaired, and thus ambulation may be impeded (Miller, undated).

The most commonly used treatment for lymphedema is complete decongestive therapy, which includes massage to drain lymph, compression bandages or clothing, exercises to improve lymph flow, and skin care. Most of these treatments can be performed at home, guided by a lymphedema therapist. Success rates are relatively high, especially for those using these treatments at least five times weekly over a three-month period (Miller, undated).

A recently developed treatment for lymphedema after cancer treatment is the pneumatic compression device, a two-phase lymph preparation and drainage device that stimulates the lymphatic system to move lymphatic fluids from areas of impaired lymphatic function to healthy areas. Garments are made with stretch material that wraps around the affected area, so no fitting process is needed. Through a programmable controller, the device applies sequential inflation and deflation to several chambers at one- and three-second intervals along the length of the garment to direct lymphatic and extravascular fluids proximally towards the axilla or other functional draining basins within the trunk. The standard treatment is 30 minutes (Gutierrez, 2020).

In April 2012, the U.S. Food and Drug Administration cleared Flexitouch pneumatic compression garment systems for treatment of several clinical indications, including limb lymphedema (U.S. Food and Drug Administration, 2012). In August 2016, the manufacturer received clearance for the Flexitouch garments designed for the head and neck area specifically to treat head and neck lymphedema (U.S. Food and Drug Administration, 2016). Approval was based on data collected from a limited market release to more than 80 adults without active cancer at least four weeks after cancer treatment to determine substantial equivalence. A majority of subjects were able to don and doff the device by the second attempt with a favorable benefit-risk profile of the device for use in the head and neck.

Findings

Guidelines

The American Cancer Society guideline for treating lymphedema after treatment for head and neck cancer makes no mention of pneumatic compression devices (Cohen, 2016). The American Head and Neck Society statement on lymphedema treatment lists several options, including compression bandages and clothing, but does not mention advanced pneumatic compression devices such as Flexitouch (Miller, undated).

A National Comprehensive Cancer Network (2025b) survivorship guideline recommends pneumatic compression for home management of lymphedema, recognizing that high-level evidence is lacking and most studies address breast cancer survivors. The Network's guideline on head and neck cancer mentions manual lymphatic decompression therapy and custom-fitted compression devices as treatment options, but not pneumatic compression devices (National Comprehensive Cancer Network, 2025a).

Evidence review

Efficacy studies of treatments for secondary lymphedema following head and neck cancer treatment consist of few randomized studies, with manual lymphatic drainage being the best studied (Tyker, 2019). Evidence of the safety and efficacy of Flexitouch advanced pneumatic compression is preliminary, consisting of one small randomized study and a few small nonrandomized studies. When used as adjunct therapy, advanced pneumatic compression devices may improve swelling and symptoms associated with secondary head and neck lymphedema. Patients were generally satisfied with the treatment, which may improve treatment compliance at

home. However, higher quality evidence from prospective, controlled, and adequately powered studies is needed to clarify the optimal timing and administration of the intervention (de-la-Cruz-Fernández, 2025).

The following large studies and reviews analyzed advanced pneumatic compression devices for treating secondary lymphedema following head and neck cancer surgery. A systematic review of 23 studies (n = 2,147) included six studies of advanced pneumatic compression devices, only one of which was randomized and controlled. The review was limited by data quality (most studies had fewer than 50 subjects). Low-quality evidence suggested that standard therapy was beneficial, as were pneumatic compression devices when used as adjunct therapy (Cheng, 2023).

A review of 16,654 head and neck cancer survivors, of which 6.5% (n = 521) were treated for lymphedema. Of these 521 patients, most had manual lymphatic drainage, and 8.6% (n = 45) were treated with advanced pneumatic compression devices. Authors reported lymphedema was underdiagnosed in this population, but advanced pneumatic compression may improve treatment, based on early evidence (Stubblefield, 2023).

A study (n = 206) of subjects with head and neck related lymphedema treated daily for at least 30 minutes with Flexitouch for at least four weeks (average 90 days) revealed significant improvement in all symptoms and function items ($P < .00001$), including ability to control lymphedema at home. A total of 71% of participants reported compliance with daily use, 87% reported they were satisfied or very satisfied, and 90% reported feeling better after treatment. Authors stated that findings support a randomized controlled trial (Gutierrez, 2020).

The only randomized controlled trial published as of this writing randomized participants with lymphedema who had completed treatment for head and neck cancer to either a group using daily advanced pneumatic compression devices (n = 24) or a wait-list control group (n = 25). The group using advanced devices had superior perceived ability to control lymphedema ($P = .003$); less visible external swelling (front view $P < .001$, right view $P = .004$, left view $P = .005$); and less reported pain (Ridner, 2021).

A survey of 44 persons with lymphedema after head and neck cancer therapy subsequently treated with Flexitouch found that 25 rated the device very/somewhat comfortable; 36 rated the treatment very/somewhat comfortable; 27 reported feeling somewhat or much better with the device; and 41 stated that home use of the device would be very or somewhat likely (Mayrovitz, 2018).

In 2022, we updated the references, deleted several older references, and identified no new relevant literature to add to the policy. No policy changes are warranted.

In 2023, we updated the references and found no newly relevant information to add. No policy changes are warranted.

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

In 2025, we updated the references and added one systematic review to the policy. No policy changes are warranted.

References

On August 28, 2025, 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 “head and neck neoplasms (MeSH),” “lymphedema (MeSH),” “Flexitouch,” “head and neck cancer,” “lymphedema,” and “pneumatic compression.” 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.

Cheng JT, Leite VF, Tennison JM, et al. Rehabilitation interventions for head and neck cancer-associated lymphedema: A systematic review. *JAMA Otolaryngol Head Neck Surg*. 2023;149(8):743-753. Doi: 10.1001/jamaoto.2023.1473.

Cohen EE, LaMonte SJ, Erb NL, et al. American Cancer Society head and neck cancer survivorship care guideline. *CA Cancer J Clin*. 2016;66(3):203-239. Doi: 10.3322/caac.21343.

de-la-Cruz-Fernández L, Galiano-Castillo N, Galván-Banqueri P, et al. Lymphedema management in patients with head and neck cancer: A systematic review of randomized controlled trials on physical therapy interventions. *Support Care Cancer*. 2025;33(5):420. Doi: 10.1007/s00520-025-09438-1.

Gutierrez 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;42(8):1791-1799. Doi: 10.1002/hed.26110.

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;40(1):137-143. Doi: 10.1002/hed.24995.

Miller M. Lymphedema. AHNS Survivorship, Supportive Care & Rehabilitation Service, American Head & Neck Society. https://www.ahns.info/survivorship_intro/topical_review-lymphedema/. Undated.

National Cancer Institute. Head and neck cancers. https://www.cancer.gov/types/head-and-neck/head-neck-fact-sheet. Last reviewed May 25, 2021.

National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Head and neck cancers. Version 2.2025. www.nccn.org. Published May 23, 2025.(a)

National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Survivorship. Version 2.2025. www.nccn.org. Published May 23, 2025.(b)

Ridner SH, Kietrich MS, Deng J, Ettema SL, Murphy B. Advanced pneumatic compression for treatment of lymphedema of the head and neck: A randomized wait-list controlled trial. *Support Care Cancer.* 2021;29(2):795-803. Doi: 10.1007/s00520-020-05540-8.

Stubblefield MD, Weycker D. Under recognition and treatment of lymphedema in head and neck cancer survivors – a database study. *Support Care Cancer*. 2023;31(4):229. Doi: 10.1007/s00520-023-07698-3.

Tyker A, Franco J, Massa ST, et al. Treatment for lymphedema following head and neck cancer therapy: A systematic review. *Am J Otolaryngol*. 2019;40(5):761-769. Doi: 10.1016/j.amjoto.2019.05.024.

U.S. Food and Drug Administration. Flexitouch® system. 501(k) Premarket notification letter K120972. https://www.accessdata.fda.gov/cdrh_docs/pdf12/K120972.pdf. Published April 13, 2012.

U.S. Food and Drug Administration. Flexitouch® system. 501(k) Premarket notification letter K153311. https://www.accessdata.fda.gov/cdrh_docs/pdf15/K153311.pdf. Published August 12, 2016.

Policy updates

3/2020: initial review date and clinical policy effective date: 5/2020

4/2020: Policy references updated.

3/2021: Policy references updated.

3/2022: Policy references updated.

3/2023: Policy references updated.

3/2024: Policy retired.

9/2025: Policy reactivated and references updated.