

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

Clinical Policy ID: CCP.1448

Recent review date: 3/2024

Next review date: 7/2025

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

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Coverage policy

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

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 (National Cancer Institute, 2021). The majority of these cancers occur in men and in persons over the age of 50. Most head and neck cancers affect the epiglottis, esophagus, glottis, hard palate, hypopharynx, oral cavity, oropharynx, palatine tonsil, pharynx, subglottis, supraglottis, tongue, or trachea.

The majority of patients present with regional spread or distant metastasis at the time of diagnosis, as only approximately 28% of head and neck cancers are diagnosed when the cancer is confined to the primary site (National Cancer Institute, 2023). Estimated five-year survival rates after diagnosis for head and neck cancers range from 18% for cancers with distant metastasis to 85% for cancers confined to the primary site. 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 patients who have been treated for head and neck cancer, especially from surgery and radiation, as up to 75% of patients will manifest some signs and symptoms of lymphedema after treatment (Miller, undated). 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. Psychological effects from physical disfigurement can also occur (Smith, 2010). A study of 103 participants with head and neck cancer found that lymphedema severity correlates with symptom burden, functional status, and quality of life (Deng, 2013).

The American Head and Neck Society states that 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 (Miller, undated). 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. A study of 1,202 participants with head and neck cancer-related lymphedema showed 60% improved after complete decongestive therapy, and treatment adherence was a significant predictor ($P < .001$) of response (Smith, 2015).

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 lymph 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 lymph and extravascular fluids proximally towards the axilla or other functional draining basins within the trunk (Adams, 2010). The standard treatment is 30 minutes (Gutierrez, 2020).

In April 2012, the U.S. Food and Drug Administration approved 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 approval to use 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

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 not pneumatic compression devices such as Flexitouch (Miller, undated).

A National Comprehensive Cancer Network 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, 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).

Persons with lymphedema who had completed treatment for head and neck cancer were randomized into a group using daily advanced pneumatic compression devices (n = 24) or a wait-list group (n = 25). The group using 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 study of phlebolymphe~~ma~~ treatment compared outcomes for Blue Cross members who used Flexitouch (n = 87) and those who used conservative treatment (n = 86) found the Flexitouch group had 59% fewer mean annual hospitalizations (.13 versus .32; $P < .001$). The study did not mention the original diagnosis, and thus did not specify head and neck cancer cases (Lerman, 2019).

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 related 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).

A systematic review of 26 studies (n = 1,018) of treatment efficacy for lymphedema after head and neck cancer treatment found that few studies are randomized, and manual lymph drainage is best studied. No mention is made of pneumatic compression devices such as Flexitouch (Tyker, 2019).

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 added a systematic review of 23 studies (n = 2,147) of persons treated for lymphedema after head and neck cancer surgery. Of these, six included advanced pneumatic compression devices, only one of which was randomized and controlled. The review was limited by data quality (most studies under 50 subjects). Low-quality evidence suggested that standard therapy was beneficial, as were pneumatic compression devices when used as adjunct therapy (Cheng, 2023).

We also added 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 report lymphedema is underdiagnosed in this population, but advanced pneumatic compression may improve treatment, based on early evidence (Stubblefield, 2023).

No policy changes are warranted.

References

On December 27, 2023, 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.

Adams KE, Rasmussen JC, Dame C, et al. Direct evidence of lymphatic function improvement after advanced pneumatic compression device treatment of lymphedema. *Biomed Opt Express*. 2010;1(1):114-125. Doi: 10.1364/BOE.1.000114.

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.

Deng J, Murphy BA, Dietrich MS, et al. Impact of secondary lymphedema after head and neck cancer treatment on symptoms, functional status, and quality of life. *Head Neck*. 2013;35(7):1026-1035. Doi: 10.1002/hed.23084.

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.

Lerman M, Gaebler JA, Hoy S, et al. Health and economic benefits of advanced pneumatic compression devices in patients with phlebo-lymphedema. *J Vasc Surg*. 2019;69(2):571-580. Doi: 10.1016/j.jvs.2018.04.028.

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 Cancer Institute. Surveillance, Epidemiology, and End Results Program. Cancer stat facts: Oral cavity and pharynx cancer. <https://seer.cancer.gov/statfacts/html/oralcav.html>. Published September, 2023.

National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Head and neck cancers. Version 2.2024. www.nccn.org. Published December 8, 2023.

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.

Smith BG, Hutcheson KA, Little LG, et al. Lymphedema outcomes in patients with head and neck cancer. *Otolaryngol Head Neck Surg*. 2015;152(2):284-291. Doi: 10.1177/0194599814558402.

Smith BG, Lewin JS. The role of lymphedema management in head and neck cancer. *Curr Opin Otolaryngol Head Neck Surg.* 2010;18(3):153-158. Doi: 10.1097/MOO.0b013e32833aac21.

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 references updated.