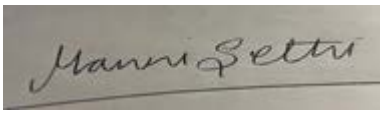
Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 4/1/2024
Policy Number: ccp.1448	**Effective Date:** 5/2020 **Revision Date:** March 1, 2024
Policy Name: Flexitouch® pneumatic compression devices for lymphedema after head and neck surgery	
Type of Submission – Check all that apply: **New Policy** **Revised Policy*** **Annual Review – No Revisions** **Statewide PDL**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** See tracked changes below.	
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Keystone First
Family of Health Plans

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.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First'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 by Keystone First 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. Keystone First'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. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First'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 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 disfiguration 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 phlebolymphedema 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.

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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.