KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria**, "Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders"** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Dysphagia is a clinical term that refers to difficulty in swallowing. It may be caused by various pathologies including neuromuscular disorders and diseases such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), Parkinson disease, and myasthenia gravis. Other etiologies for dysphagia include stroke, traumatic brain injury, head and neck tumors, ageing, generalized weakness, and other non-neurogenic causes. Dysphagia may have a major impact on the quality of life of patients and can lead to malnutrition, dehydration, or aspiration pneumonia (Park 2016).

Dysphagia may occur at any phase of the swallowing process; in the oral phase when impaired lingual movements may lead abnormal bolus formation and manipulation; in the pharyngeal phase due weakening of the pharyngeal constrictors that are crucial for the transfer of the oral bolus from the mouth to the esophagus,

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decreased hyoid bone movement, and delayed laryngeal movements leading to pharyngeal residues and aspiration; or in the esophageal stage due to impaired upper esophageal sphincter movements.

Swallowing difficulty in ALS patients may result from weakness and/or spasticity of the muscles of deglutition, including the muscles of mastication, the tongue, lips, pharynx and larynx. In addition, weakness of the respiratory and ventilatory muscles impairs the airway protection by reducing the expiratory pressure needed to produce effective cough. In MS, the swallow coordination can be disrupted by demyelination of the corticobulbar tracts, cerebellar and/or brainstem involvement and the weakness or paresis of the muscles important for the swallow function. Research showed that disruption of the neuromuscular sequencing of pharyngeal and laryngeal events during swallow occurred in up to 90% of individuals with MS. In addition, similar to ALS, the reduced strength of the expiratory muscles not provide sufficient pressure for cough production and airway clearance. The pathophysiology of oropharyngeal dysphasia in Parkinson's disease is not clearly understood but is postulated to be due to dysfunction of the brain stem, degeneration of the substantia nigra, as well as disturbance of nondopaminergic neural networks (Van hooren 2014, Park 2016, Byeon 2016, Plowman 2016, Silverman 2017).

Management of dysphagia can be broadly divided into two approaches: 1. The remedial approach with the goal of improving swallowing function through different exercises; and 2. The compensatory approach that aims at safer swallowing e.g. by controlling the material and viscosity of the food, and the use of specific postural techniques and maneuvers during the food intake. The compensatory approaches, however, have a temporary effect and cannot induce recovery of the damaged swallow network. Investigators have thus focused on the remedial approaches that aim at restoration of function. Different new therapeutic modalities for managing swallowing in neurologic disorders have been developed and introduced to practice in the recent years, such as neuromuscular electrical stimulation, deep brain stimulation, respiratory muscle training, and others (Byeon 2016, Park 2016).

Recently expiratory muscle strength training (EMST) has emerged as a potential remedial therapy for swallowing disorders. It is an exercise program that focuses on increasing the force-generating capacity of the expiratory muscles during breathing with the aim of improving the maximum expiratory pressure, voluntary coughing effectiveness, as well as improving displacement of the hyoid during swallowing. Researchers explained that during the swallowing process suprahyoid muscle contraction in the pharynx pulls the hyoid bone in the anterior superior direction, and that sufficient movement of the hyoid bone in this direction is associated with airway protection and safe swallowing such as opening of the upper esophageal sphincter during swallowing. Neurogenic disorders may result in weakness of the suprahyoid muscles (anterior belly of the digastric, mylohyoid, and geniohyoid muscles) that are important for coughing and breathing out forcefully and swallowing. Weakness of these muscles leads to insufficient movement of the hyoid bone and in turn reduces the cough capacity and airway clearance. Activation of the suprahyoid muscles during EMST is thus believed to be effective in improving swallowing. It was initially investigated in the early 2000s by a team of researchers in Florida as a swallowing rehabilitation intervention in patients with Parkinson's disease (Pitts 2012, Laciuga 2014, Eom 2017, Moon 2017, Park 2016, Pearson 2017, Silverman 2017).

Expiratory muscle training is performed by hand-held resistive or pressure threshold devices. The resistance-based devices rely on adjusting the diameter of the airflow vent holes in the device. Reducing the dimeter of the vent holes imposes resistance requiring increases respiratory muscle force. These devices have no threshold for the user to overcome and can be ineffective for strength training if used with inadequate airflow. Pressure-threshold devices on the other hand, rely on the pressure exerted during expiration. The device has a pressure threshold relief valve that opens only when a sufficient expiratory pressure is generated by the user during a forceful expiration into the device.

EMST150 device (Aspire Products, LLC; Gainesville, Florida) is a pressure-threshold handheld calibrated device that includes a one-way, spring-loaded valve with an adjustable external dial. The valve blocks the flow of air until enough pressure is produced. Once the targeted pressure is produced, the valve opens, and air begins to flow through the device. The latter allows adjusting the pressure amount in a range between 0 and 150 cm H_2O. The pressure-threshold load is based on the patient's maximum expiratory pressure (MEP) obtained through a pressure manometer. During training the pressure threshold device is adjusted incrementally to progressively increase the resistance (progressive overload). The expiratory force must be sufficient to open the spring-loaded valve and allow the air flow. The pressure released valve requires a consistent flow of air to remain open. If the expiratory force is inadequate, the valve will not open and no air will flow through the device. These mechanics may serve as a biofeedback during the use of the device. The "dose" of EMST is typically defined in terms of the number of repetitions per set, with 5 sets completed each day, for 5 days per week with the device resistance set at 75% of the patient's MEP and progressed each week (Pitts 2009, Troche 2010, Brooks 2017).

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When training ceases or the body undergoes a long period of detraining (inactivity) following a period of physical training, it loses some or all the positive gains achieved during training. This suggests that training should take place continually to maintain the benefits of an exercise program, particularly in individuals with neurodegenerative disease (https://emst150.com/faq/)

EMST is a form of therapy and is not subject to FDA regulations. The technology has not been previously reviewed by MTAC it is being reviewed based on a request form the Clinical Review Unit for decision support.

Medical Technology Assessment Committee (MTAC)

Date: 07/09/2018 MTAC REVIEW

Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders

Evidence Conclusion:

Conclusion:

- There is no published evidence to date to determine that EMST is superior or equivalent to other remedial or compensatory approaches used to manage swallowing disorders in patients with neurogenic disease or disorders.
- There is low-quality evidence showing that EMST may improve short-term swallowing outcomes, compared to no treatment in selected patients with mild to moderate dysphagia secondary to Parkinson's disease,
- There is low-quality evidence showing that EMST may improve short-term swallowing outcomes in patients with dysphagia secondary to acute/subacute stroke, compared to no active treatment. The benefits observed in the sham therapy groups may suggest that the EMST has a placebo effect, or that dysphagia may improve as a natural recovery of the condition and not due to the intervention.
- The benefits observed in the sham therapy groups in neurogenic conditions other than stroke may also indicate a placebo effect of the EMST, or that expiratory breathing alone without the positive pressure load can improve the MEP.
- There is insufficient evidence to determine whether the short-term benefits observed with EMST therapy compared to sham treatment would last after treatment cessation.
- Adverse outcomes were not reported in any of the trials.

The use of Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders doesn't meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/07/2018	08/07/2018 MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC, 08/01/2023MPC, 11/05/2024MPC	08/07/2018

MPC Medical Policy Committee

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Revision History	Description
08/07/2018	Added MTAC review from 7/9/18 and created document

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