



**Kaiser Foundation Health Plan
of Washington**

Clinical Review Criteria

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

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA 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.

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, KPWA 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, 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 diameter 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 H₂O. 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).

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 from 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:

The published studies that investigated the benefit of expiratory muscle strength training in patients with dysphagia due to neurogenic disease are limited in quantity and quality. The majority examined pre-post effect of EMST among patients with swallowing disorders secondary to Parkinson's disease (PD) and were conducted by the team of investigator who developed the EMST150 device. The published RCTs that used EMST in patients with PD or other neurologic disorders compared the therapy to sham treatment and not to any other remedial or compensatory approaches to determine whether it has equivalent or superior effect to the traditional therapies used for the management of dysphagia. The trials were too small with attrition bias, and examined the effect of the therapy only for the duration of expiratory training (4-5 weeks), which does not allow examining the durability of effect after discontinuation of the therapy. In addition, the published trials generally included patients in the early stages of the disease/disorder or those with mild to moderate dysphagia and may not be generalized to more severe or advanced cases who may not benefit from or tolerate the treatment.

Effects of EMST on dysphagia secondary to Parkinson's disease

Troche et al's, 2010 RCT (Evidence table 1) compared EMST versus sham treatment in 68 participants with mild to moderate dysphagia secondary to Parkinson's disease. The primary outcome was improvement in swallowing safety using penetration-aspiration score (PAS). Secondary outcomes included swallow physiology as assessed by hyoid movement and UES opening, as well as swallow quality of life and respiratory measure (maximum expiratory pressure [MEP]).

After 4 weeks of active or sham EMST training, patients in the active therapy group showed statistically significant improvement in the PAS compared to baseline values, while those undergoing sham therapy group did not show a significant improvement. The authors calculated a NNT of 5 to gain on additional improvement and a NNT of 2 for a net benefit improvement with the use of EMST. The results also showed that EMST group had significant improvements in the upper esophageal sphincter (UES) opening, UES widest, and UES closure, but with no significant improvement in hypoid elevation duration. Both the active and sham therapy groups showed some improvement in the swallow quality of life. The adherence to therapy and adverse events were not discussed. The study was randomized and controlled. However, it was a short-term study that compared EMST to a sham treatment and not to an alternative active therapy. In addition, the authors compared pre-post outcomes within each group and not between groups. The trial included patients with mild to moderate impairment in swallowing due to PD and its results may not be generalized to severe swallowing impairment in patients with PD, or to swallowing dysfunction due to other diseases or disorders.

A very small follow-up study (Troche, 2014) explored changes in MEP and PAS three months after the end of EMST training among 10 participants selected from the original trial and showed no statistically significant deterioration in MEP or PAS three months post completion of the EMST regimen. The authors reported that the detraining effects on swallow safety was less clear and concluded that the results of this study indicate that there is a need for the development of maintenance programs to sustain function following intensive periods of training. It is worth noting that the device used in the trial EMST150 was initially developed by the principal investigators of the trial.

In a study published by a single author (Byeon, 2017), 33 patients with dysphagia caused by Parkinson's disease were randomly assigned to receive EMST using EMST150 device (n=18) or EMST plus postural techniques (n=15). The postural techniques included chin tucking, head rotation, head tilting, bending head back and lying down straight for 30 minutes per session. The therapy was given 5 days a week for 4 weeks. The primary outcome was swallowing recovery measured by video fluoroscopic studies (VFS). The results of the trial showed a decrease in mean VSF scale score in both groups after treatment, but the decrease in the combined intervention group was significantly greater than in the EMST-only group. The study was a small RCT, with short follow-up duration, and conducted mainly among men, all of which would limit generalization of the results.

Effects of EMST on dysphagia secondary to stroke

There were three small RCTs, (Park et al, 2019 [n=27] Moon et al, 2017 [n=18] and Eom et al, 2017 [N=40]) published to date, that investigated the effect of a 4-week EMST on suprahyoid muscle activity and airway aspiration in patients with oropharyngeal dysphagia secondary to acute/subacute stroke. The trials were conducted by the same team of principal investigators in university hospitals in Korea, which makes it difficult to rule out a potential overlap between the participants. All three trials had similar protocol, intervention, outcome

measures, and results. To avoid introducing bias by duplication the results for the overlapping participants, the largest and most recent trial (Eom et al, 2017) was selected for critical appraisal.

Eom and colleagues' trial (2017) (Evidence table 2) randomized 33 patients >65 years of age with dysphagia due to stroke to undergo active EMST therapy using EMST150 device or to a sham therapy using a nonfunctional EMST system with no loading device. The two groups underwent training for 4 weeks (5 sets of 5 breaths 5 days a week for 4 weeks). All participants were assessed by fluoroscopic swallowing study (VFSS) before and after the intervention. The primary outcome was improvement in swallowing assessed by video fluoroscopic scale (VDS) and safety measured by in laryngeal penetration score (PAS). Only 26 (78.8%) of the participants completed the study.

The overall results of the study showed that the 2 groups improved in both the oral and pharyngeal phases of the VDS and the PAS after the 4 weeks of therapy compared to baseline. The improvements observed were significantly better in the active treatment group.

The study was randomized, controlled, and had objective outcomes. However, it was a very small trial, conducted among patients with subacute stroke and the improvement, as observed in the placebo group, may be due to the natural neurological recovery of the condition and not due to the intervention. In addition, the study period was only four months and insufficient to determine the long-term durability of the observed effects.

Effects of EMST on dysphagia secondary to multiple sclerosis

Silverman and colleagues' (2017) sham controlled RCT (Evidence table 3) examined the effect of EMST on the swallowing function and swallow-related quality of life in 42 patients with MS. 36 completed the maximum pressure expiratory (MEP) test and were randomized, and n=32 completed 5-week study. Sixteen patients underwent EMST using the EMST150 device and twenty patients underwent a sham therapy using the EMST150 device without an internal pressure threshold spring. All participants were instructed to complete 5 sets of five repetitions (total of 25 times in approximately 20 minutes /day) 5 days a week for 5 weeks. The primary outcomes were the change in MEP, penetration aspiration score (PAS), and improvement swallow quality-of-life (SWAL-QOL). MEP was obtained weekly to monitor and adjust the device, and video fluoroscopy was used to record swallow function and measure PAS.

The overall results showed improvement in MEP in the two study groups with no significant difference between them. The improvement in the sham group and lack of statistical significance between the 2 groups suggests that simple expiratory breathing alone without the positive pressure load can improve the MEP in patients with MS. The results also show that PAS improved in 40% in the EMST and 14% in the sham group. There was no significant difference between the 2 groups in the total swallow score.

The study was randomized, controlled, blinded, and had objective outcomes. However, it was a very small trial, with no power analysis, unclear method of randomization and allocation concealment, only 76% of the enrolled participants completed the trial, and there was no ITT analysis. In addition, the study period was only five weeks, does not allow examining the long-term durability of observed benefit, and the authors had financial ties with the industry.

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*.

Date Created	Date Reviewed	Date Last Revised
08/07/2018	08/07/2018 ^{MPC}	

^{MPC} Medical Policy Committee

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

Codes

No specific codes