CLINICAL MEDICAL POLICY	
Policy Name:	Electrical Stimulation for Oropharyngeal Dysphagia
Policy Number:	MP-099-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	11/01/2024; 01/01/2024; 12/01/2022; 03/01/2022; 12/21/2020; 11/18/2019
Effective Date:	12/01/2024; 02/01/2024; 01/01/2023; 04/01/2022; 01/18/2021; 11/18/2019
Next Annual Review:	10/2025
Revision Date:	10/16/2024; 10/18/2023; 10/19/2022; 10/20/2021; 10/21/2020
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

Policy History

Date	Activity
12/01/2024	Provider Effective date
10/16/2024	QI/UM Committee Review
10/16/2024	Annual Review: No changes to Experimental/Investigational stance. Updated 'Summary of Literature' section.
02/01/2024	Provider Effective date
12/01/2023	PARP Approval (Sent to PARP to advise that policy is listed as 'pre-service/postpayment' and is not Prior Auth, therefore does not need to be sent for PARP approval)
10/18/2023	QI/UM Committee review
10/18/2023	Annual Review: No changes to E/I clinical stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
01/01/2023	Provider Effective date
10/19/2022	QI/UM Committee review
10/19/2022	Annual Review: No changes to clinical stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
04/01/2022	Provider effective date
02/07/2022	PARP Approval
10/20/2021	QI/UM Committee review
10/20/2021	Annual Review: No clinical criteria changes. Added TAG determination information. Updated Summary of Literature and Reference sections.
01/18/2021	Provider effective date

08/13/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ does not provide coverage under the benefits of the Company's Medicaid products for electrical stimulation for oropharyngeal dysphagia because it is considered investigational and, therefore, not medically necessary.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Dysphagia - A condition in which the individual experiences difficulty swallowing. This can be the result of underlying causes such as stroke and other neurologic conditions, local trauma, muscle damage, or tumor that obstructs the passage of foods.

Oropharyngeal Dysphagia - A form of dysphagia where the individual has difficulty with the initial phases of a swallow.

Procedures

1. Electrical stimulation for the treatment of oropharyngeal dysphagia is considered experimental and investigational, and therefore, not medically necessary. There is currently insufficient peer-reviewed medical literature to support the use of electrical stimulation for oropharyngeal dysphagia. Electrical stimulation can include transcutaneous electrical stimulation, neuromuscular electrostimulation and/or pharyngeal electrical stimulation.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

3. Place of Service
   The proper place of service for electrical stimulation for the treatment of oropharyngeal dysphagia is outpatient.

Governing Bodies Approval

VitalStim is a hand-held electrical stimulator that received FDA approval on June 11, 2007. The FDA approval states that the VitalStim therapy is a comprehensive electrotherapy device for treating patients suffering from dysphagia. It is a prescription device administered to patients or under the direction of a licensed healthcare provider in hospitals, post-acute care facilities, nursing homes and outpatient clinics. Indications for use include muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

The Centers for Medicare and Medicaid Services (CMS) has not published any guidance on this topic.

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

As of November 2005, the TAG workgroup assigned electrical stimulation for dysphagia an Option # 4, specifically for CPT/HCPCS codes 92526, E0731, and E0745.

Summary of Literature

Dysphagia is a condition in which the individual experiences difficulty swallowing. Some common symptoms of dysphagia include inability to control food or saliva in the mouth, gurgling or wet voice sound after swallowing, difficulty initiating swallowing, pain with swallowing, coughing, choking and/or a sense of food being lodge in the esophagus.

Dysphagia may be the result of several diseases such as progressive neurodegenerative diseases (multiple sclerosis, amyotrophic lateral sclerosis, Parkinson's and Alzheimer's), non-progressive motor disease (cerebral palsy), autoimmune diseases, inflammatory muscle conditions, diseases of the esophagus, respiratory diseases (asthma and COPD), stroke and brain tumors. Dysphagia is a common occurrence in the elderly as a result of weakened jaw muscles, loss of teeth and reduced saliva production.

The World Gastroenterology Organization (WGO) estimates that one in 17 people will develop some form a dysphagia in their lifetime. In addition, WGO estimates that dysphagia affects 40-70% of patients with stroke, 60-80% of patients with neurodegenerative diseases, up to 13% of adults aged 65 and older, greater than 51% of institutionalized elderly patients and 60-75% of patients undergoing radiotherapy for head and neck cancer (WGO, 2014).

Treatment for oropharyngeal dysphagia is typically directed at the underlying cause. Persistent dysphagia requires treatment based on maintenance of hydration, nutrition and prevention of complications such as aspiration. Standard treatments for the management of dysphagia include:

- Speech, occupational, and physical therapy as part of a plan of swallowing rehabilitation
- Appropriate postural, nutritional, and behavioral modifications
- Placement of percutaneous feeding tube

Treatment of dysphagia may consist of traditional swallowing training, behavioral training and pharmacological therapies that focus on enhancing sensory feedback from the oropharynx to the central pattern generator, strengthening the disused or pharyngeal musculature, preventing atrophy and reduced motor output from the central pattern generator, and minimizing symptoms through the use of compensatory postural adjustments. Recently, adjunctive therapies have been introduced, which include repetitive transcranial magnetic stimulation and transcranial direct current stimulation, and surface neuromuscular electrical stimulation (NMES), which is commonly used in rehabilitation departments (Alamer, 2020).

Electrical stimulation was introduced as a modality for dysphagia rehabilitation more than a decade ago. The underlying premise of this modality is improving the structural movements and enhancing neural activation based on stimulation-induced muscle contractions. However, divisive evidence exists regarding the effectiveness of this treatment modality. Many studies have been conducted to understand the impact of electrical stimulation on different aspects of swallowing function. However, more studies are needed to understand the effect of electrical stimulation parameters on swallowing physiology (Barikroo, 2020).

Rationale

An updated review of randomised controlled trials of interventions for people with dysphagia post-stroke was conducted. The objective was to assess the effects of swallowing therapy on death or dependency among stroke survivors with dysphagia within six months of stroke onset. There were 27 new studies were identified since the previous update in 2012 for a total of 41 trials. The study assessed the efficacy

of swallowing therapy overall and in subgroups by intervention. Interventions included: acupuncture (11 studies), behavioral interventions (9studies), drug therapy (3 studies), drug therapy (3 studies), neuromuscular electrical stimulation (NMES 6 studies), pharyngeal electrical stimulation (4 studies), physical stimulation (3 studies), transcranial direct stimulation (2 studies), and transcranial magnetic stimulation (9 studies). The authors concluded that moderate- and low-quality evidence suggested that swallowing therapy did not have a significant effect on the outcomes of death or dependency/disability, case fatality or penetration aspiration score. It was noted swallowing therapy may have reduced length of hospital stay, dysphagia, and chest infections and may have improved swallowing. However, the results were based on evidence of variable quality, involving a variety of interventions. The authors recommend that further high-quality trials be conducted to test specific interventions for effectiveness (Bath et al. 2018).

A systemic review and meta-analysis of eight randomized control trials on the effects of surface neuromuscular electrical stimulation on post-stroke dysphagia was conducted by Chen and colleagues (2016). It was reported that the studies were low-to-moderate in quality and there was a limited number of studies with significant heterogeneity. The clinical trials provided limited evidence that use of neuromuscular electrical stimulation was significantly more effective that swallow treatment alone for post-stroke dysphagia.

A preliminary study with 20 participants found that application of NMES to the masseter muscle had a therapeutic effect on oral dysfunction of patients after subacute stroke. Hence, NMES of the masseter muscle could represent a viable treatment option for oral dysfunction after stroke. Additionally, chewing might play an important role in stimulating the initiation of the swallowing process. Thus, NMES of the masseter muscle could also enhance the chewing process. Improvement of the oral phase might facilitate the swallowing process as a whole. However, future studies with a larger number of participants focusing on the oral phase are necessary to confirm findings of this study (Lee, 2019).

A systematic review of the effectiveness of neuromuscular electrical stimulation (NMES) for the treatment of dysphagia recommended carrying out further studies with reliable methodology to establish the most adequate application parameters for NMES and determine the most appropriate combination of techniques to be performed simultaneously and in the same session. This will help to establish new protocols on the use of NMES for the treatment of DP with the aim of reaching the best effects in the shortest time possible (Diéguez-Pérez, 2020).

A systematic review concluded that NMES has been found to improve the swallowing function of patients with dysphagia after stroke. Although this systematic review found that NMES is effective in improving swallowing function compared to other interventions, great attention is needed when NMES are used for post- stroke dysphagic subjects such as the course of disease duration and its severity. Further research should be conducted on NMES efficacy on chronic stroke patients with swallowing dysfunction (Alamer, 2020).

Coding Requirements

Non-covered Procedure Codes
These procedure codes will not be reimbursed without Medical Director approval.

CPT Code	Description
92526	Treatment of swallowing dysfunction and/or oral function for feeding
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
HCPCS Code	**Description**
E0720	Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation
E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)
E0745	Neuromuscular stimulator, electronic shock unit

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

Pennsylvania Department of Human Services. Technology Assessment Group (TAG) Coverage Decisions. Managed Care Operations Memorandum: OPS # 11/2005-026, November 1, 2005. Option #4. Accessed on September 27, 2023.

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