



Geisinger Health Plan Policies and Procedure Manual

Policy: MP131

Section: Medical Benefit Policy

Subject: VitalStim

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: VitalStim

II. Purpose/Objective:

To provide a policy of coverage regarding VitalStim

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

VitalStim is a device being marketed for use in the treatment of dysphagia. The device uses synchronized neuromuscular electrical stimulation delivered via surface electrodes in an attempt to initiate or strengthen the pharyngeal muscle contractions required in swallowing, and also to attempt to retrain pharyngeal nerves and muscles.

EXCLUSIONS:

There is insufficient data in the published, peer-reviewed medical literature at this time to support the efficacy of VitalStim when used as a stand-alone procedure or as the sole treatment of swallowing dysfunction and/or oral function for feeding.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Freed ML, Freed L, Chatburn RL, Christian M., Electrical stimulation for swallowing disorders caused by stroke. Respiratory Care. 46(5):466-474. 2001.

ECRI, HTAIS Hotline Response. Neuromuscular Electrical Stimulation for Dysphagia. Feb 2004.

Hayes Inc. Online. Neuromuscular Electrical Stimulation for Muscle Rehabilitation. April 2003.

Leelamanit V, Limsakul C, Geater A., Synchronized electrical stimulation in treating pharyngeal dysphagia. Laryngoscope 112(12):2204-2210. Dec. 2002.

Geisinger Technology Assessment Committee Triage Group. Vital Stim. Feb 2004.

Burnett TA, Mann EA, Cornell SA, Ludlow CL. Laryngeal elevation achieved by neuromuscular stimulation at rest. Journal fo Applied Physiology 2003;94:128-134.

FDA White Paper. Use of Electrical Stimulation to Restore Swallowing Function. VitalStim Therapy. www.vitalstim.com

Burnett TA, Mann EA, Stoklosa JB, Ludlow CL. Self-triggered functional electrical stimulation during swallowing. J Neurophysiol 2005 December;94(6):4011-8.

Winifred S. Hayes. Hayes Directory (online). Electrical Stimulation for the treatment of Oropharyngeal Dysphagia. June 6, 2006.

Shaw GY, Sechtem PR, Searl J, Keller K, Rawi TA, Dowdy E. Transcutaneous neuromuscular electrical stimulation (VitalStim) curative therapy for severe dysphagia: myth or reality? Ann Otol Rhinol Laryngol. 2007 Jan;116 (1):36-44.

Langdon C., Blacker D. Dysphagia in Stroke: A New Solution. 2010 May.

Novitas Solutions Local Coverage Determination (LCD): Speech-Language Pathology (SLP) Services: Dysphagia; Includes VitalStim ® Therapy (L34891) 10/1/15

Frost J, Robinson HF, Hibberd J. A comparison of neuromuscular electrical stimulation and traditional therapy, versus traditional therapy in patients with longstanding dysphagia. Curr Opin Otolaryngol Head Neck Surg. 2018;26(3):167-173.

Park JS, Oh DH, Hwang NK, Lee JH. Effects of neuromuscular electrical stimulation in patients with parkinson's disease and dysphagia: A randomized, single-blind, placebo-controlled trial. *NeuroRehabilitation*. 2018;42(4):457-463.

Lee KW, Kim SB, Lee JH, Lee SJ, Park JG, Jang KW. Effects of Neuromuscular Electrical Stimulation for Masseter Muscle on Oral Dysfunction After Stroke. *Ann Rehabil Med*. 2019;43(1):11-18.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 03/04

Revised: 3/05 (Refs); 03/06(refs); 3/07, 3/08,

Reviewed: 3/09, 3/10, 5/11, 5/12, 5/13, 5/14, 5/15, 5/16, 4/17, 4/18, 4/19, 4/20, 4/21, 4/22, 4/23, 4/24

CMS UM Oversight Committee Approval: 12/23, 7/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.