

Policy: MP131

Section: Medical Benefit Policy

Subject: VitalStim

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

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit 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.

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

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