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Subject: Vagus Nerve Stimulation
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Clinical Documentation and Prior Authorization Required	√	Type of Review - Case Management	
Not Covered		Type of Review – Precertification Department	√
		Administrative Process (Internal Use Only)	RN

Note: Background, product, and disclaimer information is located at the end of this document.

Overview

Vagus Nerve Stimulation (VNS) uses a technique in which electrical pulses are delivered to the cervical portion of the vagus nerve by an implanted generator. The device, “NeuroCybernetic Prosthesis (NCP)[®] System,” is manufactured by Cyberonics, and is also known as the VNS Therapy System[™].

Coverage Guidelines

Tufts Health Plan may authorize coverage of Vagus Nerve Stimulation for Members with the diagnosis of partial onset seizures, when **one** of the following criteria are met:

- The Member has remained refractory to optimal anti-epileptic medications and/or surgical intervention.
- The Member experiences debilitating side effects from anti-epileptic medication.

Limitations

According to the Tufts Health Plan Evidence of Coverage (EOC), a treatment or procedure is considered experimental or investigative “if reliable evidence shows that prevailing opinion among experts regarding the treatment is that more studies or clinical trials are necessary to determine its safety, efficacy, toxicity, maximum tolerated dose, or its efficacy as compared with a standard means of treatment or diagnosis.”

In accordance with the above definition, Tufts Health Plan considers the use of Vagus Nerve Stimulation to be experimental and investigational for all indications other than partial onset seizures, including, but not limited to:

- Depression
- Autism
- Alzheimer’s disease
- Obsessive-compulsive disorder
- Obesity

Codes

The following HCPCS/CPT codes require prior authorization:

Code	Description
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for implanted neurostimulator, replacement only

References

1. Carpenter, L., Moreno, F., Kling, M., et al. Effect of vagus nerve stimulation on cerebrospinal fluid monoamine metabolites, norepinephrine, and gamma-aminobutyric acid concentrations in depressed patients. *Journal of Biological Psychiatry*. 2004; 56: 418-426.
2. Hayes, Inc. Vagus nerve stimulation for epilepsy. Hayes Medical Technology Directory. December 9, 2007.
3. Hayes, Inc. Vagus nerve stimulation for depression. Hayes Medical Technology Directory. February 3, 2005.
4. Hayes, Inc. Vagus nerve stimulation for depression. Hayes Medical Technology Directory. Update Search. May 8, 2007.
5. Sackeim, H., Rush, A., George, M., et al. Vagus nerve stimulation (VNS™) for treatment-resistant depression: efficacy, side effects, and predictors of outcome. *Neuropsychopharmacology*. 2001; 25 (5).

Approval History

Reviewed by the Clinical Coverage Criteria Committee on September 15, 2006. New criteria

Subsequent Endorsement Date(s) and Changes Made:

- April 25, 2007: Reviewed and renewed without changes
- April 30, 2008: Reviewed and renewed without changes
- May 4, 2009: Reviewed and renewed without changes
- August 5, 2009 for January 1, 2010 effective date: CPT Code 64553 (Percutaneous implantation of neurostimulator electrodes; cranial nerve) added to codes requiring prior authorization.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for Tufts Health Plan benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. Tufts Health Plan makes coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to all fully insured Tufts Health Plan products unless otherwise noted in this guideline or the Member's benefit document. This guideline does not apply to Tufts Health Plan Medicare Preferred or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. Providers in the New Hampshire service area are subject to CIGNA HealthCare's provider arrangement for the purpose of CareLinkSM.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.