

Subject: Implantable Neurostimulators

Background: Implantable neurostimulators are micro-electronic devices that deliver stimulation to the nervous system and offer various therapeutic treatment options. Deep brain stimulation (DBS) involves constant, high-frequency electrical stimulation of specific sites in the brain with implanted electrodes as a means to reduce the symptoms of movement disorders such as essential tremor and Parkinson's disease. Gastric electrical stimulation (GES) therapy is a treatment for individuals with chronic gastroparesis, a gastrointestinal motility disorder characterized by delayed gastric emptying without evidence of physical obstruction. The implanted stimulator delivers electrical impulses to the gastric muscles to stimulate gastric myoelectric activity, which improves stomach emptying and reduces the frequency and severity of symptoms.

Sacral nerve stimulation has been recently introduced as an alternative, minimally invasive treatment option for individuals with chronic, severe fecal incontinence who fail first-line conservative therapies or who are not appropriate candidates for such therapies, and who are considering a more invasive surgical option. Spinal cord stimulation (SCS) involves the electrical stimulation of spinal nerves using electrodes implanted in the epidural space of the spinal column. The goal of SCS is to suppress pain in specific areas for individuals with chronic pain, including chronic, refractory, neuropathic pain. Vagus nerve stimulation (VNS) is a therapy for treatment-resistant major depression and bipolar disorder in which an implanted generator, the neurocybernetic prosthesis, delivers electrical pulses to the cervical portion of the vagus nerve. The goal of VNS is to reduce the severity and/or duration of a depressive period.

Authorization:

Prior authorization is required for covered implantable stimulators provided to members enrolled in commercial (HMO, POS, and PPO) products.

Policy and Coverage Criteria:

Harvard Pilgrim Health Care (HPHC) considers implantable neurostimulators as reasonable and medically necessary with a request from an accredited provider with appropriate state licensure and when documentation confirms specific criteria for ANY of the following devices:

Deep Brain Stimulators

- Unilateral or bilateral Deep Brain Stimulators are considered reasonable and medically necessary when documentation confirms member has ANY of the following:
 - Member age 7 years or older requires treatment of intractable primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), OR
 - Member has medically refractory essential tremors, OR
 - Member has medically intractable Parkinson's disease including ALL the following:
 - Levodopa-responsive; AND
 - Motor complications refractory to pharmacologic therapy; AND
 - Minimal score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale when the individual has been without medication for approximately 12 hours

Gastric Stimulators

- Gastric Stimulators are considered reasonable and medically necessary when documentation confirms member is experiencing severe gastroparesis of idiopathic or diabetic origin, and ALL the following:
 - Condition is refractory to prokinetic and antiemetic medications, or documentation confirms that use of such medications is contraindicated; AND
 - Scintigraphy confirms delayed gastric emptying.

Sacral Nerve Stimulators for Urinary Incontinence

- Temporary trial of Sacral Nerve Stimulators is considered reasonable and medically necessary when documentation confirms member has urinary incontinence or frequency, and confirms ALL the following:
 - Positive peripheral nerve evaluation test for urinary urge incontinence and urinary urgency/frequency; AND
 - Diagnosis of urinary urgency with or without incontinence, urinary urgency associated with frequency and/or nocturia in the absence of infection or other pathology, OR non-obstructive urinary retention unrelated to a neurologic condition; AND
 - Documented failure of, or symptoms refractory to, at least two types of conservative therapies, (e.g. behavioral interventions, dietary modifications, bladder training, trial of anticholinergic or beta agonist medications); AND
 - Urinary incontinence is experienced for a minimum of 12 months and is not related to other neurologic conditions that is associated with secondary manifestations of urinary urge incontinence, urgency, frequency or non-obstructive urinary retention.
- Permanent Sacral Nerve Stimulators are considered reasonable and medically necessary when documentation confirms member meets criteria for temporary trial of sacral nerve stimulators for urinary incontinence and has undergone a successful trial based on ALL the following:
 - Member has at least a 50% reduction in catheter volume/catheterization;
 - Member has at least 50% reduction in ONE of the following:
 - Daily incontinence episodes, OR
 - Severity of the episodes or the number of pads/diapers used per day
 - Member has at least 50% improvement in ONE of the following:
 - Number of voids daily, OR
 - Volume per void, OR
 - Frequency per void

Sacral Nerve Stimulators for Fecal Incontinence

- Temporary trial of Sacral Nerve Stimulators is considered reasonable and medically necessary when documentation confirms member has fecal incontinence, and confirms ALL the following:
 - More than 2 episodes of fecal incontinence per week for 6 consecutive months, or for 12 consecutive months following vaginal childbirth; AND
 - Incontinence is not related to another neurologic condition (e.g. peripheral neuropathy, spinal cord injury)
 - Documented failure of conservative therapies for at least 12 months, (e.g. medication, dietary modification), or symptoms or refractory to conservative therapies.
- Permanent Sacral Nerve Stimulators are considered reasonable and medically necessary when documentation confirms member meets criteria for temporary trial of sacral nerve stimulators for fecal incontinence and has undergone a successful trial of at least 50% improvement in symptoms.

Spinal Cord Stimulators

- Temporary trial of Spinal Cord Stimulators is considered reasonable and medically necessary for treatment of chronic intractable pain secondary to complex regional pain syndrome (CRPS) when documentation confirms member has chronic, intractable neuropathic pain of the trunk or limbs, and ALL the following:

- Failure of at least 6 months of conservative treatment (e.g., pharmacotherapy, physical therapy, and/or surgery), or documentation confirms contraindications to conservative treatment; AND
- Pain is neuropathic in nature (e.g. failed back surgery syndrome, complex regional pain syndrome, phantom limb/stump pain and peripheral neuropathy)
- Permanent Spinal Cord Stimulators are considered reasonable and medically necessary when documentation confirms member meets criteria for temporary trial of spinal cord stimulators and has undergone a successful trial of at least 50% improvement in symptoms.

Vagal Nerve Stimulator

- Vagal Nerve Stimulators are considered reasonable and medically necessary when documentation confirms ALL the following:
 - Member with refractory seizures experiences persistent seizures and/or intolerable side effects after trials of 2 or more antiepileptic medications; AND
 - Member has failed, or is not a candidate for, resective surgery

Exclusions:

Harvard Pilgrim Health Care (HPHC) considers implantable neurostimulators as not medically necessary for all other indications. In addition, HPHC does not cover:

- Deep brain stimulation for conditions including, but not limited to:
 - Chronic cluster headache
 - Degenerative disorders
 - Depression
 - Drug-induced movement disorder
 - Infectious diseases
 - Metabolic disorders
 - Multiple Sclerosis (MS)
 - Obsessive-Compulsive Disorder (OCD)
 - Tourette Syndrome
 - Trauma
- Gastric stimulation for any other indication, including obesity
- Sacral nerve stimulation for conditions including, but not limited to:
 - Anorectal malformation;
 - Chronic inflammatory bowel disease;
 - Chronic pelvic pain;
 - Constipation;
 - Fecal incontinence following non-cancer related rectal surgery within the past 12 months, or cancer-related rectal surgery within the past 24 months;
 - Stress incontinence or other chronic voiding dysfunction due to neurologic conditions (e.g., spinal cord injury, diabetic neuropathy, MS)
 - Urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia)
- Spinal nerve stimulation for conditions including, but not limited to:
 - Refractory angina pectoris
 - Pain associated with malignancy
 - Treatment of critical limb ischemia
 - Cancer-related pain
 - Heart failure
- Vagus stimulation for conditions including, but not limited to:
 - Addictions
 - Alzheimer's disease
 - Anxiety disorder

- Asthma
- Autism spectrum disorder
- Back and neck pain
- Bipolar disorder
- Bulimia
- Cerebral palsy
- Crohn's Disease
- Chronic pain syndrome
- Cluster headaches
- Depression
- Essential tremor
- Fibromyalgia
- Heart failure
- Migraines
- Morbid obesity
- Narcolepsy
- Obsessive-compulsive disorder
- Paralysis agitans
- Sleep disorders
- Tinnitus
- Traumatic brain injury
- Tourette's syndrome
- Cerebellar stimulation/pacing for any indication
- Occipital nerve stimulation for any indication
- Tibial nerve stimulation for any indication
- gammaCore®
- Peripheral nerve stimulation

Supporting Information:

According to a 2015 Cochrane Review, vagus nerve stimulation (VNS) for partial seizures appears to be an effective and well tolerated treatment. Results of the overall efficacy showed that VNS stimulation using high stimulation paradigm was significantly better than low stimulation in reducing the frequency of seizures.

The Academy of Neurology (AAN) published 2011 guidelines that recommend deep brain stimulation as a treatment option for individuals with Parkinson's Disease to reduce motor fluctuations, dyskinesia and medication usage.

The National Institute for Health and Care Excellence (2017) recommends offering deep brain stimulation for individuals with advanced Parkinson's disease whose symptoms cannot be adequately controlled by best medical therapy.

Guidelines:

The National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7) indicates two general classifications of electrical nerve stimulators that are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

Use of peripheral stimulators involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than 1/2 inch. Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually

necessitates an operating room. Peripheral nerve stimulators may also be employed to assess an individual's suitability for continued treatment with an electric nerve stimulator.

There are two types of implantations covered by central nervous system stimulators: dorsal column (spinal cord) neurostimulation and depth brain neurostimulation. The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

- The implantation of the stimulator is used only as a late resort (if not a last resort) for individuals with chronic intractable pain;
- With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given individual;
- Individuals have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the individual must be available; and
- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

The American College of Gastroenterology (ACG, 2013) recommends scintigraphic gastric emptying of solids as standard for the evaluation of gastric emptying and the diagnosis of gastroparesis. Documented delay in gastric emptying is required for diagnosis of gastroparesis.

Coding:

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

CPT® Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical
61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical
61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
61868	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative

	microelectrode recording; each additional array (List separately in addition to primary procedure)
61870	Craniectomy for implantation of neurostimulator electrodes, cerebellar; cortical
61880	Revision or removal of intracranial neurostimulator electrodes
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
64550	Application of surface (transcutaneous) neurostimulator
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse 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 (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

Billing Guidelines:

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:

1. Abdi, S. Prevention and management of complex regional pain syndrome in adults. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
2. Chronic migraine. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
3. DBS Epilepsy Fact Sheet. Medtronic Inc.; 2018. Accessed May 3, 2019.

HPHC Medical Policy

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HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.

4. Deep Brain Stimulation for Parkinson's Disease. National Institute for Health and Care Excellence (NICE); 2017. Available at: <https://www.nice.org.uk/guidance/ipg19/resources/deep-brain-stimulation-for-parkinsons-disease-pdf-52773986491333>. Accessed May 3, 2019.
5. Deep brain stimulation for treatment of obsessive-compulsive disorder. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
6. Deep Brain Stimulation for Treatment-Resistant Depression. Hayesinc.com/subscribers [via subscription only]. Accessed May 3, 2019.
7. Depression in adults: Overview of neuromodulation procedures. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
8. Epilepsy Bibliography. Medtronic Inc.; 2018. Accessed May 3, 2019.
9. Evaluation and management of drug-resistant epilepsy. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
10. Fecal incontinence in adults: Management. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
11. Gormley, EA., Lightner, DJ., Faraday, M., et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment. J Urol. 2015; 193(5): 1572.
12. Implantable Sacral Nerve Stimulation for Urinary Voiding Dysfunction. Hayesinc.com/subscribers [via subscription only]. Accessed May 3, 2019.
13. Management of Gastroparesis. Giorg. 2013. Available at: <https://gi.org/guideline/management-of-gastroparesis/>. Accessed May 3, 2019.
14. Medical Technology Directory. Gastric electrical stimulation for gastroparesis. Hayesinc.com/subscribers [via subscription only]. Accessed May 3, 2019.
15. Medtronic DBS Therapy for Epilepsy. U.S. Food and Drug Administration; 2018. Accessed June 3, 2019.
16. National Coverage Determination (NCD) for Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24). <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=279&ncdver=1&bc=AAAAGAAAAAAAAA%3d%3d&>
17. National Coverage Determination (NCD) for Sacral Nerve Stimulation for Urinary Incontinence (230.18) <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=249&ncdver=1&bc=AAAAGAAAAAAAAA%3d%3d&>
18. National Coverage Determination (NCD) for Vagus Nerve Stimulation (VNS) (1670.18). <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=230&ncdver=2&bc=AAAAGAAAAAAAAA%3d%3d&>
19. Occipital Nerve Stimulation for Chronic Cluster Headache and Chronic Migraine. Hayesinc.com/subscribers [via subscription only]. Accessed May 3, 2019.
20. Overview of the treatment of chronic pain. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
21. Panebianco M, Zavanone C, Dupont S, Restivo D, Pavone A. Vagus nerve stimulation therapy in partial epilepsy: a review. Acta Neurologica Belgica. 2016;116(3):241-248. doi:10.1007/s13760-016-0616-3.
22. Spinal Cord Stimulation for Relief of Neuropathic Pain. Hayesinc.com/subscribers [via subscription only]. Accessed May 3, 2019.
23. Stewart, F., Gameiro, OL., El Dib, R., et al. Electrical stimulation with non-implanted electrodes for overactive bladder in adults. Cochrane Database Syst Rev. 2016; 4: CD010098.
24. Summary of Safety and Effectiveness Data (SSED). U.S. Food and Drug Administration; 2018. Accessed May 3, 2019.
25. Surgical treatment of essential tremor. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
26. Surgical treatment of Parkinson disease. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
27. Treatment of dystonia. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
28. Treatment of urinary incontinence in women. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
29. Vagus Nerve Stimulation for Depression. Hayesinc.com/subscribers [via subscription only]. Accessed May 3, 2019.

30. Vagus Nerve Stimulation for Epilepsy. Hayesinc.com/subscribers [via subscription only]. Accessed May 3, 2019.
31. Vagus nerve stimulation therapy for the treatment of epilepsy. UpToDate.com/login [via subscription only]. Accessed May 3, 2019.
32. Zesiewicz T, Elble R, Louis E et al. Evidence-based guideline update: Treatment of essential tremor: Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2011;77(19):1752-1755. doi:10.1212/wnl.0b013e318236f0fd.

Summary of Changes

Date	Change
6/19	Annual review; no changes
3/18	Background and references updated; policy coverage criteria refined
3/17	Updated coding to reflect deleted code
8/16	Updated references. Minor formatting changes.

Approved by Medical Policy Committee: 6/12/19

Approved by Clinical Policy Operational Committee: 2/15; 8/16; 3/17; 3/18; 6/19

Policy Effective Date: 06/14/19

Initiated: 7/1/15

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