Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Implantable Neurostimulators

Effective: July 1, 2024

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; 800-232-0816

☐ Tufts Health Plan Commercial products; 617-972-9409

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

☐ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☒ Harvard Pilgrim Health Care Stride Medicare Advantage; 888-609-0692

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

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.

Clinical Guideline Coverage Criteria

Harvard Pilgrim Health Care uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. For Harvard Pilgrim Health Care Medicare Advantage plan members, the following NCDs are being used:

- Deep brain stimulation for Parkinson and essential tremor: NCD - Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24) (cms.gov)
- Deep brain and spinal cord stimulation: NCD - Electrical Nerve Stimulators (160.7) (cms.gov)
- Neuromuscular Electrical Stimulation NCD - Neuromuscular Electrical Stimulation (NMES) (160.12) (cms.gov)
- Vagus nerve stimulation NCD - Vagus Nerve Stimulation (VNS) (160.18) (cms.gov)

Limitations

Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers implantable neurostimulators as not medically necessary for all other indications. In addition, HPHC does not cover:

1. Deep brain stimulation for ANY of the following:
    a. Chronic cluster headache
    b. Degenerative disorders
    c. Depression
    d. Drug-induced movement disorder
    e. Infectious diseases
    f. Metabolic disorders
    g. Multiple Sclerosis (MS)
    h. Obsessive-Compulsive Disorder (OCD)
    i. Tourette Syndrome
    j. Trauma
2. Cerebellar stimulation/pacing for any indication
3. Occipital nerve stimulation for any indication (e.g., cervicogenic headaches)
4. Tibial nerve stimulation for any indication
5. Vagal nerve stimulation for resistant depression
6. gammaCore®
7. Peripheral nerve stimulation
8. Deep brain stimulation for essential tumor or Parkinson's disease with any of the following:
    a. Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes
    b. Cognitive impairment, dementia, or depression, which would be worsened by or would interfere with the patient's ability to benefit from DBS
    c. Current psychosis, alcohol abuse or other drug abuse
    d. Members with structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder
    e. Members with previous movement disorder surgery within the affected basal ganglion
    f. Members with significant medical, surgical, neurologic or orthopedic co-morbidities contraindication DBS surgery or stimulation
    g. Members exposed to diathermy (deep heat treatment including shortwave diathermy, microwave, and ultrasound diathermy) or any type of MRI, which may adversely affect the DBS system or affect the brain around the implanted electrodes

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
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

Code	Description
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)
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
63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
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

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Approval And Revision History

June 2020: Reviewed by the Medical Policy Approval Committee (MPAC); criteria, limitations, overview, and references updated

Subsequent endorsement date(s) and changes made:

- May 2021: Reviewed by MPCC; criteria updated
- May 18, 2022: Reviewed by Medical Policy Approval Committee (MPAC); renewed without changes
- November 16, 2023: Reviewed by MPAC, template updated, updated criteria, effective January 1, 2024
- December 1, 2023: reviewed and approved by UM Committee effective January 1, 2024
- June 13, 2024: Reviewed by UM Committee, renewed without changes effective July 1, 2024
- June 20, 2024: Reviewed by MPAC, renewed without changes effective July 1, 2024

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make 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 and 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

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. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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.