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 implantation of any of the following devices:
- Vagal Nerve Stimulators
- Deep Brain Stimulators
- Gastric Stimulators
- Sacral Nerve Stimulators
- Spinal Cord Stimulators

Policy and Coverage Criteria:
Harvard Pilgrim Stride℠ (HMO) Medicare Advantage covers the implantation of certain types of neurostimulators when use of the implantable device(s) is reasonable and medically necessary to treat a member with conditions (listed below).

The covered services must be:
• Reasonable and medically necessary based on the member’s condition, complexity of requested service(s), and accepted standards of clinical practice.
• An essential part of active treatment of the member’s medical condition, and ordered under a plan of care established and reviewed regularly by the attending physician caring for the member; and
• Furnished by provider(s) with appropriate state licensure, and accreditation/certification from an appropriate accrediting organization.

Deep Brain Stimulators
Unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulators (DBS) are considered reasonable and medically necessary for treatment of essential tremor (ET) and/or Parkinsonian tremor when devices are FDA approved and documentation confirms ALL the following:
• Diagnosis of ET based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic Parkinson’s disease (presence of at least 2 cardinal Parkinson’s disease features (tremor, rigidity or bradykinesia)) which is of a tremor dominant form; AND
• Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy; AND
• Member’s willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, and stimulator settings.

Unilateral or bilateral subthalamic nucleus (STN) or globus pallidus interna (GPI) DBS is considered reasonable and medically necessary for the treatment of Parkinson’s disease when devices are FDA approved and documentation confirms ALL the following:
• Diagnosis of Parkinson’s disease based on the presence of at least 2 cardinal Parkinson’s disease features (tremor, rigidity or bradykinesia); AND
• Advanced idiopathic Parkinson’s disease as determined by the use of Hoehn and Yahr stage or Unified Parkinson’s disease Rating Scale (UPDRS) part III motor subscale; AND
• Persistent disabling Parkinson’s symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling “off” periods) despite optimal medical therapy; AND
• Member’s willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, and stimulator settings.

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

Sacral Nerve Stimulators for Urinary Incontinence, Urgency-Frequency Syndrome, and Urinary Retention
• Temporary trial of sacral nerve stimulators is considered reasonable and medically necessary when documentation confirms member has urinary incontinence or frequency, with documented failure of, or symptoms refractory to, at least two types of conservative therapies, (e.g., medication, exercises)
• Permanent sacral nerve stimulators are considered reasonable and medically necessary when member meets the criteria for temporary trial of sacral nerve stimulators for urinary incontinence AND have undergone a trial of stimulation deemed successful based on ALL the following outcomes:
  o Members have at least a 50% reduction in catheter volume/catheterization.
  o 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
  o 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:
  o More than 2 episodes of fecal incontinence per week for 6 months, or for 12 months following vaginal childbirth; AND
  o Incontinence is not related to another neurologic condition (e.g., peripheral neuropathy, spinal cord injury); AND
  o Documented failure of conservative therapies, (e.g., medication, dietary modification), or symptoms 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 neuropathic pain secondary to complex regional pain syndrome (CRPS) when documentation confirms member has chronic, intractable neuropathic pain of the trunks or limbs and ALL the following:
  o Failure of at least 6 months of conservative treatment (e.g., pharmacotherapy, physical therapy, and/or surgery), or contraindication to conservative treatment; AND
  o Pain is neuropathic in nature (e.g., failed back surgery syndrome, complex regional pain syndrome, phantom limb/stump pain and peripheral neuropathy)
  o Member has undergone physical and psychological evaluation prior to implantation
  o Implantation of the stimulator is used only as a last resort for members with chronic intractable pain
• 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 Stimulators
• Vagal nerve stimulators are considered reasonable and medically necessary when documentation confirms ALL the following:
  o Members with refractory seizures experience persistent seizures and/or intolerable side effects after trials of 2 or more antiepileptic medications; AND

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Exclusions:
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers implantable neurostimulators as not medically necessary for all other indications. In addition, HPHC does not cover:
- Deep brain stimulation for ANY of the following:
  - 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 but not limited to treatment of obesity, people without gastroparesis, autonomic nervous system disorders other than gastroparesis]
- 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)
- Cerebellar stimulation/pacing for any indication
- Occipital nerve stimulation for any indication (e.g., cervicogenic headaches)
- Tibial nerve stimulation for any indication
- Vagal nerve stimulation for resistant depression
- gammaCore®
- Peripheral nerve stimulation
- Deep brain stimulation for essential tumor or Parkinson's disease with any of the following:
  - Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes
  - Cognitive impairment, dementia or depression, which would be worsened by or would interfere with the patient's ability to benefit from DBS
  - Current psychosis, alcohol abuse or other drug abuse
  - Members with structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder
  - Members with previous movement disorder surgery within the affected basal ganglion
  - Members with significant medical, surgical, neurologic or orthopedic co-morbidities contraindication DBS surgery or stimulation
  - 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
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.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>43647</td>
<td>Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum</td>
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<tr>
<td>43881</td>
<td>Implantation or replacement of gastric neurostimulator electrodes, antrum, open</td>
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<tr>
<td>43882</td>
<td>Revision or removal of gastric neurostimulator electrodes, antrum, open</td>
</tr>
<tr>
<td>61850</td>
<td>Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical</td>
</tr>
<tr>
<td>61860</td>
<td>Cranietomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical</td>
</tr>
<tr>
<td>61863</td>
<td>Twist drill, burr hole, craniotomy, or cranietomy 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</td>
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<tr>
<td>61864</td>
<td>Twist drill, burr hole, craniotomy, or cranietomy 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)</td>
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<td>61867</td>
<td>Twist drill, burr hole, craniotomy, or cranietomy 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</td>
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<tr>
<td>61868</td>
<td>Twist drill, burr hole, craniotomy, or cranietomy 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)</td>
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<tr>
<td>61880</td>
<td>Revision or removal of intracranial neurostimulator electrodes</td>
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<tr>
<td>61885</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array</td>
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<tr>
<td>61886</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays</td>
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<td>61888</td>
<td>Revision or removal of cranial neurostimulator pulse generator or receiver</td>
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<td>63650</td>
<td>Percutaneous implantation of neurostimulator electrode array, epidural</td>
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<td>63655</td>
<td>Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural</td>
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<tr>
<td>63663</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
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<td>63685</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrode array; cranial nerve</td>
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<tr>
<td>CPT® Code</td>
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<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed</td>
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<td>64568</td>
<td>Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
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<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
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<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<tr>
<td>64595</td>
<td>Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</td>
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<td>95970</td>
<td>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</td>
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<td>95971</td>
<td>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</td>
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<td>95972</td>
<td>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</td>
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<td>95980</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming</td>
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<td>95981</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming</td>
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<tr>
<td>95982</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming</td>
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**Summary of Changes:**

<table>
<thead>
<tr>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>5/22</td>
<td>Annual Review; no changes</td>
</tr>
<tr>
<td>5/21</td>
<td>Annual review; criteria updated</td>
</tr>
<tr>
<td>6/20</td>
<td>Annual review; criteria, exclusions, supporting information and references updated</td>
</tr>
<tr>
<td>3/17</td>
<td>Coding updates</td>
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</tbody>
</table>

Approved by Medical Policy Committee: 5/18/22
Approved by Clinical Policy Operational Committee: 8/15; 3/17; 7/20; 5/21; 6/22
Policy Effective Date: 6/30/22
Initiated: 8/15

*Harvard Pilgrim Stride℠ (HMO) policies are based on medical science and relevant information including current Medicare coverage (including National and Local Coverage Determinations), Harvard Pilgrim medical policies, and Harvard Pilgrim Stride℠ (HMO) Medicare Advantage Plan materials. These policies are intended to provide benefit coverage information and guidelines specific to the Harvard Pilgrim Stride℠ (HMO) Medicare Advantage Plan. Providers are responsible for reviewing the CMS Medicare Coverage Center guidance; in the event that there is a conflict between this document and the CMS Medicare Coverage Center guidance, the CMS Medicare Coverage Center guidance will control.*