STRIDE[sm] (HMO) MEDICARE ADVANTAGE

Effective Date: April 14, 2017

Subject: Implantable Neurostimulators

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[SM] (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).

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.

Criteria:

Stimulator	Criteria
Deep Brain Stimulator • **Unilateral** • **Bilateral**	Unilateral deep brain stimulation is authorized when medical record documentation confirms member has medically refractory essential tremor. Unilateral or bilateral deep brain stimulation is authorized when medical record documentation confirms 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). • Member has medically intractable Parkinson's disease including ALL the following: ➢ Levadopa responsive; ➢ Motor complications refractory to pharmacologic therapy;

Stimulator	Criteria
	➢ Minimal score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale when the patient has been without medication for approximately 12 hours.
Gastric Stimulation for Gastroparesis	Authorized when medical record documentation confirms member is experiencing severe gastroparesis of idiopathic or diabetic origin, and ALL the following; 1. Condition is refractory to prokinetic and antiemetic medications, or use of such medications is contraindicated*; AND 2. Scintigraphy confirms delayed gastric emptying. *Documentation confirming contraindication is required.
Sacral Nerve Stimulation	**For Urinary Incontinence:** • **A temporary trial of sacral nerve stimulation is authorized when medical record documentation confirms member has urinary incontinence or frequency, and meets ALL the following:** 1. Positive peripheral nerve evaluation test for urinary urge incontinence and urinary urgency/frequency; 2. Diagnosis of refractory urge incontinence, urge/frequency incontinence, OR non-obstructive urinary retention unrelated to a neurologic condition; 3. Documented failure of, or symptoms refractory to, at least two types of conservative therapies, (e.g. medication, exercises) • **Implantation of a permanent sacral nerve stimulator is authorized for members who met the criteria listed above, AND have undergone a successful trial of sacral nerve stimulation.** ➢ A successful trial of a temporary sacral nerve stimulator results in ANY of the following: ▪ Urinary retention: At least a 50% reduction in catheter volume/catheterization; ▪ Urinary urge incontinence: At least 50% reduction in one of the following: daily incontinence episodes, severity of the episodes or the number of pads/diapers used per day; ▪ Urinary urge/frequency: At least 50% improvement in one of the following: number of voids daily, volume per void and frequency per void. **For Fecal Incontinence:** • **A temporary trial of sacral nerve stimulation is authorized when medical record documentation confirms ALL the following:** 1. More than 2 episodes of fecal incontinence per week for 6 months, or for 12 months following vaginal childbirth; 2. Documented failure of conservative therapies, (e.g. medication, dietary modification), or symptoms or refractory to conservative therapies. • **Implantation of a permanent stimulator is authorized for members who meet criteria listed above and have undergone a successful**

Stimulator	Criteria
	trial of sacral nerve stimulation. ➢ A successful trial is defined as at least a 50% improvement in symptoms.
Spinal Cord Stimulation for Pain	**A temporary trial of spinal cord stimulation is authorized when medical record documentation confirms member has chronic, intractable neuropathic pain of the trunk or limbs, and ALL the following:** 1. Failure of at least 6 months of conservative treatment (e.g., pharmacotherapy, physical therapy, and/or surgery), or contraindication* to conservative treatment; 2. Pain is neuropathic in nature (e.g. failed back surgery syndrome, complex regional pain syndrome, phantom limb/stump pain and peripheral neuropathy) *Documentation confirming contraindication is required. • **Implantation of a permanent spinal cord stimulator is authorized for members who met criteria listed above and have undergone a successful trial of spinal cord stimulation.** ➢ A successful trial is defined as at least a 50% improvement in pain relief.
Vagal Nerve Stimulator	Implantation is authorized when medical record documentation confirms ALL the following: 1. Member with refractory seizures experiences persistent seizures and/or intolerable side effects after trials of 2 or more antiepileptic mediations; 2. Member has failed, or is not a candidate for, resective surgery.

Exclusions:

Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage does not cover implantable neurostimulators when criteria above are not met; this includes ALL the following:

1. 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
2. Gastric stimulation for any indication not listed above (including obesity)
3. Sacral nerve stimulation for ANY of the following:
   - 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).

4. Cerebellar stimulation/pacing for any indication
5. Occipital nerve stimulation for any indication
6. Tibial nerve stimulation for any indication

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® Code	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 (eg, 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 (eg, 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 (eg, 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 (eg, 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
61875	Craniectomy for implantation of neurostimulator electrodes, cerebellar; subcortical
61880	Revision or removal of intracranial neurostimulator electrodes
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or

CPT® Code	Description
	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
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrode array
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 (eg, 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 (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

References:

1. CMS NCD for Electrical Nerve Stimulators-160.7(accessed 8/17/15)
2. CMS NCD for Neuromuscular Electrical Stimulators- 160.12 (accessed 8/17/15)
3. CMS NCD for Supplies Use in the Delivery of TENS and NMES- 160.13 accessed 8/17/15)
4. CMS NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18) (accessed 8/17/15)
5. CMS LCD: Peripheral Nerve and Peripheral Nerve Field Stimulation (L33199) (accessed 8/17/15)

Summary of Changes:

Date	Change
3/17	Coding updates

Approved by UMCPC: 3/22/17
Reviewed/Revised: 8/15; 3/17
Initiated: 8/15