Harvard Pilgrim Health Care | TUFTS Health Plan

Point32Health companies

Medical Necessity Guidelines:
Implantable Neurostimulators

Effective: October 1, 2026

Prior Authorization Required **If REQUIRED, submit supporting clinical documentation (electronically recommended or by fax)**	Yes ☒ No ☐
Notification Required	Yes ☐ No ☒

Applies to:

- Harvard Pilgrim Health Care Commercial products
- Tufts Health Plan Commercial products
- Tufts Health Direct
- Tufts Health Together
- Tufts Health RITogether
- Tufts Health One Care

We recommend submitting prior authorization electronically. If you opt to submit prior authorization requests via fax, please refer to this reference chart for the appropriate fax number (varies by product).
For details on all our products, please visit the Our Plans page on our provider website. For additional Prior Authorization and Notification details on other lines of business not listed on our Medical Necessity Guidelines page, please also reference our Prior Authorization Resources page.

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.

For Harvard Pilgrim Health Care Members:

This policy utilizes InterQual® criteria and/or tools, which Harvard Pilgrim may have customized. You may request authorization and complete the automated authorization questionnaire via HPHConnect at www.harvardpilgrim.org/providerportal. In some cases, clinical documentation may be required to complete a medical necessity review. Please submit required documentation as follows:

- Clinical notes/written documentation – via HPHConnect Clinical Upload or secure fax (800-232-0816)

Providers may view and print the medical necessity criteria and questionnaire via HPHConnect for providers (Select Researched and the InterQual® link) or contact the commercial Provider Service Center at 800-708-4414. (To register for HPHConnect, follow the instructions here). Members may access materials by logging into their online account (visit www.harvardpilgrim.org, click on Member Login, then Plan Details, Prior Authorization for Care, and the link to clinical criteria) or by calling Member Services at 888-333-4742

For Tufts Health Plan Members:

To obtain InterQual® SmartSheets™"

- **Tufts Health Plan Commercial Plan products:** If you are a registered Tufts Health Plan provider click here to access the Provider Website. If you are not a Tufts Health Plan provider, please click on the Provider Log-in and follow instructions to register on the Provider website or call Provider Services at 888-884-2404
- **Tufts Health Public Plans products:** InterQual® SmartSheet(s) available as part of the prior authorization process

Tufts Health Plan requires the use of current InterQual® Smartsheet(s) to obtain prior authorization.

In order to obtain prior authorization for procedure(s), choose the appropriate InterQual® SmartSheet(s) listed below. The completed SmartSheet(s) must be sent to the applicable fax number indicated above, according to Plan

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.

The Plan 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 **Tufts Health One Care** plan members, the following NCDs are being used:

- Stereotactic Introduction, Subcortical Electrodes- and Spinal Cord Stimulator Insertion: NCD - Electrical Nerve Stimulators (160.7) (cms.gov)
- Sacral Nerve Stimulation for Urinary Incontinence NCD - Sacral Nerve Stimulation For Urinary Incontinence (230.18) (cms.gov)
- Vagus Nerve Stimulation NCD - Vagus Nerve Stimulation (VNS) (160.18) (cms.gov)
- Gastric Stimulation: For the service of gastric stimulation, evidence is sufficient for coverage for gastroparesis. Gastric stimulation is a treatment modality to be considered for Member's when all other treatment options have been tried, failed, or are ineffective for gastroparesis. See InterQual criteria
- Sacral Nerve for Fecal Incontinence: NCD - Sacral Nerve Stimulation For Urinary Incontinence (230.18) and CMS LCD from a different jurisdiction to be used: LCD - Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence (L39543)

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

The Plan requires the use of the following InterQual® Subsets or SmartSheets to obtain prior authorization for the following implantable neurostimulator services:

1. Gastric Stimulation
2. Stereotactic Introduction, Subcortical Electrodes:
    a. Stereotactic Introduction Cortical Electrodes
    b. Stereotactic Introduction Subcortical Electrodes
        i. Note: The Plan covers subcortical electrodes for Members ages 7 and older when InterQual criteria for primary dystonia are met.
3. Spinal Cord Stimulator Insertion
    a. Spinal Cord Temporary Electrode Trial
    b. Spinal Cord Stimulator Insertion

In addition, The Plan 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:

***Sacral Nerve Neuromodulation/Stimulation for Urinary Incontinence: Temporary Trial**

The Plan considers a temporary trial of sacral serve stimulation as reasonable and medically necessary with an external stimulator for either percutaneous nerve evaluation or an implanted lead, when documentation confirms **ALL** the following:

1. Diagnosis, **One** of the following:
    a. Urge incontinence or urgency-frequency syndrome in the absence of infection or other pathology, **or**
    b. Overactive bladder; **or**
    c. Non-obstructive urinary retention unrelated to a neurologic condition; **and**
2. Urinary voiding dysfunction is not secondary to a neurologic condition (e.g., Parkinson's disease, stroke, spinal cord injury, multiple sclerosis, peripheral neuropathy); **and**
3. Documented failure or intolerance to at least **Two** types of conservative therapies for at least 12 months:
    a. Behavioral therapy; **or**
    b. Pelvic floor muscle exercise training; **or**
    c. Bladder training (e.g., prompted voiding); **or**
    d. Pharmacologic treatment (e.g., trial of anticholinergic/antimuscarinics or beta agonist medications).

***Sacral Nerve Neuromodulation/Stimulation for Urinary Incontinence: Permanent**

The Plan considers a permanent sacral nerve neuromodulation device as reasonable and medically necessary when documentation confirms the member has met criteria above (1-3) for a temporary trial of sacral nerve stimulation and Member has undergone a successful trial based on **ONE** of the following:

1. For urinary retention, at least a 50% reduction in catheter volume/catheterization; **or**
2. For urinary urge incontinence, at least 50% reduction in **One** of the following:
    a. Daily incontinence episodes; **or**
    b. Severity of the episodes or the number of pads/diapers used per day; **or**
3. For urinary urgency/frequency, **One** of the following:
    a. At least 50% reduction in number of voids daily; **or**
    b. At least 50% increase in volume per void.

*** Sacral Nerve Neuromodulation/Stimulation for Fecal Incontinence: Temporary Trial**

The Plan considers a temporary trial of sacral nerve neuromodulation as reasonable and medically necessary for the treatment of fecal incontinence when documentation confirms **ALL** the following:

1. More than 2 episodes of fecal incontinence per week for 6 consecutive months, or for 12 consecutive months following vaginal childbirth; **and**
2. Fecal incontinence is not related to another neurologic condition (e.g., Parkinson's disease, stroke, spinal cord injury, multiple sclerosis, peripheral neuropathy); **and**
3. Fecal incontinence is not related to an anorectal malformation (e.g., congenital anorectal malformation) or chronic inflammatory bowel disease; **and**
4. Documented failure of conservative therapies for at least 6 months, (e.g., medication, bowel training, pelvic floor rehabilitation, dietary modification).

***Sacral Nerve Neuromodulation/Stimulation for Fecal Incontinence: Permanent**

The Plan considers a permanent sacral nerve neuromodulation device as reasonable and medically necessary for the treatment of fecal incontinence when documentation confirms the member has met criteria above (1-4) for a temporary trial and Member has undergone a successful trial with at least 50% improvement in symptoms.

***Vagus Nerve Stimulator**

The plan considers vagal nerve stimulators as reasonable and medically necessary when 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 medications; **and**
2. Member has failed, or is not a candidate for, resective surgery.

*For these services, prior authorization for **Harvard Pilgrim Health Care Commercial Members** must be submitted through the automated authorization questionnaire via HPHConnect at www.harvardpilgrim.org/providerportal. For **Tufts Health Plan Commercial and Public Plan Members** please submit prior authorization to the following Fax numbers:

- Tufts Health Plan Commercial: 617-972-9409
- Tufts Health Direct: 888-415-9055
- Tufts Health Together: 888-415-9055
- Tufts Health RITogether: 857-304-6404
- Tufts Health One Care: 857-304-6304

Note: For non-implantable percutaneous tibial nerve stimulation for voiding dysfunction please see the Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction Medical Necessity Guideline. For hypoglossal nerve stimulation for the treatment of obstructive sleep apnea see the Surgical Procedures for Obstructive Sleep Apnea Medical Necessity Guidelines.

Limitations

The Plan considers Implantable Neurostimulators as not medically necessary for all other indications. In addition, The Plan does not cover:

1. Subcortical/Cortical Electrodes and Deep Brain stimulation for conditions including, but not limited to:
    a. Chronic Cluster headache
    b. Degenerative disorders
    c. Depression
    d. Drug-induced movement disorder (e.g., Tardive Dyskinesia)
    e. Multiple Sclerosis (MS)
    f. Obsessive-Compulsive Disorder (OCD)
    g. Tourette Syndrome
    h. Trauma
2. Gastric stimulation for any other indication, including obesity
3. Sacral nerve stimulation for conditions including, but not limited to:
    a. Anorectal malformation
    b. Chronic inflammatory bowel disease
    c. Chronic pelvic pain
    d. Constipation
        i. Fecal incontinence following non-cancer related rectal surgery within the past 12 months, or cancer-related rectal surgery within the past 24 months
        ii. Stress incontinence or other chronic voiding dysfunction due to neurologic conditions (e.g., spinal cord injury, diabetic neuropathy, MS
        iii. Urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia)
4. Spinal cord stimulation for conditions including, but not limited to:
    a. Refractory Canadian Class III or IV Angina
    b. Pain associated with malignancy
    c. Treatment of critical limb ischemia
    d. Cancer-related pain
    e. Heart failure
    f. Diabetic Neuropathy
    g. Chronic Intractable Back Pain without Prior Spine Surgery
5. Vagus stimulation for conditions including, but not limited to:
    a. Addictions
    b. Alzheimer's disease
    c. Anxiety disorder
    d. Asthma
    e. Autism spectrum disorder
    f. Back and neck pain
    g. Bipolar disorder
    h. Bulimia
    i. Cerebral palsy
    j. Crohn’s Disease
    k. Chronic pain syndrome
    l. Cluster headaches
    m. Depression
    n. Essential tremor
    o. Fibromyalgia
    p. Heart failure
    q. Migraines
    r. Morbid obesity
    s. Narcolepsy
    t. Obsessive-compulsive disorder
    u. Paralysis agitans
    v. Sleep disorders
    w. Tinnitus

x. Traumatic brain injury
y. Tourette's syndrome

6. Cerebellar stimulation/pacing for any indication
7. Occipital nerve stimulation for any indication
8. gammaCore®
9. Peripheral Nerve Stimulation for any indication
10. Restorative neurostimulation

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes – Gastric Stimulation

Code	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

Table 2: CPT/HCPCS Codes – Stereotactic Introduction, Subcortical Electrodes

Code	Description
61720	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus
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 (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array
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 (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array
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
61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)

Table 3: CPT/HCPCS Codes – Spinal Cord Stimulator Insertion

Code	Description
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

Code	Description
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, requiring pocket creation between electrode array and pulse generator or receiver

Table 4: CPT/HCPCS Codes – Sacral Nerve Stimulator for Urinary Incontinence Temporary Trial

Code	Description
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

Table 5: CPT/HCPCS Codes – Sacral Nerve Stimulator for Urinary Incontinence Permanent

Code	Description
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

Table 6: CPT/HCPCS Codes – Sacral Nerve Stimulator for Fecal Incontinence Temporary Trial

Code	Description
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

Table 7: CPT/HCPCS Codes – Sacral Nerve Stimulator for Fecal Incontinence Permanent

Code	Description
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

Table 8: CPT/HCPCS Codes – Vagus Nerve Stimulation

Code	Description
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
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64568	Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator

References:

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Approval And Revision History

October 21, 2020: Reviewed by the Medical Policy Approval Committee (MPAC); renewed without changes

Subsequent endorsement date(s) and changes made:

- November 10, 2020: Fax number for Unify updated
- December 16, 2020: Reviewed at IMPAC. Dorsal root ganglion stimulation covered for CRPS diagnosis affecting trunk/limbs when InterQual criteria for SCS insertion are met
- October 20, 2021: Reviewed by IMPAC, renewed without changes
- February 1, 2022: Template Updated
- October 19, 2022: Criteria added for Gastric Stimulation, Stereotactic Introduction, Sacral Nerve Stimulation for Fecal Incontinence, Sacral Nerve Stimulation for Urinary Incontinence, and Vagus Nerve Stimulation; coding updated for Integration between Harvard Pilgrim Health Care and Tufts Health Plan, effective February 1, 2023.
- November 16, 2022: Reviewed by MPAC, renewed without changes
- June 21, 2023: Reviewed by MPAC. Prior authorization requirement removed from CPT codes 95961, 95970, 95972, 95980, 95981, 95982 effective, August 1, 2023
- September 20, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Rebranded Unify to One Care, updated overview, coding updated effective January 1, 2024
- December 1, 2023: Reviewed and approved by the UM Committee, effective January 1, 2024
- June 13, 2024: Reviewed and approved by the UM Committee
- June 20, 2024: Reviewed by MPAC for 2024 InterQual Upgrade, effective August 1, 2024
- October 17, 2024: Reviewed by MPAC, limitations clarification effective December 1, 2024
- January 15, 2025: Coding clarification
- April 16, 2025: Reviewed at MPAC, renewed without changes, effective May 16, 2025.
- May 21, 2025: Reviewed by MPAC for 2025 InterQual Update, added prior authorization to CPT code 61889 effective July 1, 2025
- October 15, 2025: Reviewed by MPAC, added limitation that the Plan will not cover restorative neurostimulation effective December 1, 2025
- November 12, 2025: Fax number for Senior Care Options, Tufts Medicare Preferred HMO and Tufts Medicare Preferred PPO updated; language for Carelink removed; Harvard Pilgrim Health Care Stride Medicare Advantage removed as an applicable product from the template
- December 17, 2025: Reviewed by MPAC, sacral nerve stimulator content for both urinary and bowel incontinence revised, effective February 1, 2026.
- May 20, 2026: Reviewed by MPAC for 2026 InterQual Update and Annual Review, effective July 1, 2026.
- August 19, 2026: Reviewed by MPAC, updated Sacral Nerve Stimulation coverage for One Care to CMS criteria, administrative update in limitation #4 effective October 1, 2026
- September 15, 2026: Reviewed by UM Committee, updated Sacral Nerve Stimulation coverage for One Care to CMS criteria, administrative update in limitation #4 effective October 1, 2026

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.