Medical Necessity Guidelines: Implantable Neurostimulator

Effective: August 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

Applies to:
COMMERCIAl Products
☒ Tufts Health Plan Commercial products; Fax: 617.972.9409
• CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products
☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404
☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products
• Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
• Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

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.

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

Tufts Health Plan requires the use of an InterQual SmartSheet to obtain prior authorization for the following Implantable Neurostimulators

Clinical Coverage Criteria

The Plan requires the use of an InterQual SmartSheet to obtain prior authorization for implantable neurostimulators when they meet Medical Necessity Guidelines and are determined to be medically necessary as defined below:

I. The following are for procedures that require an InterQual SmartSheet

The plan requires the use of an InterQual SmartSheet to obtain prior authorization for certain procedures. Please note the information in the plan Modification to InterQual section(s) when indicated.

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

I.A. Gastric Stimulation

<table>
<thead>
<tr>
<th>CODES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastric Stimulation</td>
</tr>
</tbody>
</table>

The following CPT codes require prior authorization:
### I.B. Stereotactic Introduction, Subcortical Electrodes

InterQual SmartSheets

- **Stereotactic Introduction Cortical Electrodes**
- **Stereotactic Introduction Subcortical Electrodes**

### The Plan Modification to InterQual

The Plan covers subcortical electrodes for members ages 7 and older when applicable InterQual criteria for primary dystonia are met.

### CODES

The following CPT codes require prior authorization:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>61720</td>
<td>Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus</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>Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical</td>
</tr>
<tr>
<td>61863</td>
<td>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</td>
</tr>
<tr>
<td>61867</td>
<td>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</td>
</tr>
<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>
</tr>
<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>
</tr>
</tbody>
</table>
I.C. Spinal Cord Stimulator Insertion

InterQual SmartSheets

- Spinal Cord Temporary Electrode Trial
- Spinal Cord Stimulator Insertion

II. The following are procedures with the Plan Medical Necessity Guidelines

II.A Sacral Nerve Stimulators for Urinary Incontinence: Temporary Trial

Coverage Guidelines

Temporary trial of Sacral Nerve Stimulators with an external stimulator for either percutaneous nerve evaluation or an implanted lead is considered reasonable and medically necessary when documentation confirms member has urinary incontinence or frequency, and confirms ALL the following:

- 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.

Codes

The following CPT codes require prior authorization:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed</td>
</tr>
<tr>
<td>64581</td>
<td>Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
</tr>
</tbody>
</table>

II.B Sacral Nerve Stimulators for Urinary

Coverage Guidelines

The following CPT codes require prior authorization:

<table>
<thead>
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<th>Code</th>
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</thead>
<tbody>
<tr>
<td>63650</td>
<td>Percutaneous implantation of neurostimulator electrode array, epidural</td>
</tr>
<tr>
<td>63655</td>
<td>Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural</td>
</tr>
<tr>
<td>63663</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63685</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
</tbody>
</table>
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

### Codes

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<td>64581</td>
<td>Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
</tr>
</tbody>
</table>

**II.C Sacral Nerve Stimulators for Fecal Incontinence: Temporary Trial**

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.

### Codes

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<tbody>
<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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<tr>
<td>64581</td>
<td>Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
</tr>
</tbody>
</table>
II.D Sacral Nerve Stimulators for Fecal Incontinence: Permanent

**Coverage Guidelines**
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.

**Codes**
The following CPT codes require prior authorization

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed</td>
</tr>
<tr>
<td>64581</td>
<td>Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
</tr>
</tbody>
</table>

II.E Vagus Nerve Stimulator

**Coverage Guidelines**
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

**Codes**
The following CPT codes require prior authorization

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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>
</tr>
<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>
</tr>
<tr>
<td>61888</td>
<td>Revision or removal of cranial neurostimulator pulse generator or receiver</td>
</tr>
<tr>
<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrode array; cranial nerve</td>
</tr>
<tr>
<td>64568</td>
<td>Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
</tr>
</tbody>
</table>

Note: For non-implantable percutaneous tibial nerve stimulation for voiding dysfunction please see the Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction Medical Necessity Guideline

**LIMITATIONS**
The Plan considers Implantable Neurostimulators as not medically necessary for all other indications. In addition, The Plan does not cover:
- Subcortical/Cortical Electrodes and Deep Brain stimulation for conditions including, but not limited to:
  - Chronic Cluster headache
  - Degenerative disorders
  - Depression
• Drug-induced movement disorder (e.g., Tardive Dyskinesia)
• 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:
  o Anorectal malformation
  o Chronic inflammatory bowel disease
  o Chronic pelvic pain
  o 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:
  o Refractory Canadian Class III or IV Angina
  o Pain associated with malignancy
  o Treatment of critical limb ischemia
  o Cancer-related pain
  o Heart failure
  o Diabetic Neuropathy
  o Chronic Intractable Back Pain with Prior Spine Surgery

• Vagus stimulation for conditions including, but not limited to:
  o Addictions
  o Alzheimer's disease
  o Anxiety disorder
  o Asthma
  o Autism spectrum disorder
  o Back and neck pain
  o Bipolar disorder
  o Bulimia
  o Cerebral palsy
  o Crohn's Disease
  o Chronic pain syndrome
  o Cluster headaches
  o Depression
  o Essential tremor
  o Fibromyalgia
  o Heart failure
  o Migraines
  o Morbid obesity
  o Narcolepsy
  o Obsessive-compulsive disorder
  o Paralysis agitans
  o Sleep disorders
  o Tinnitus
  o Traumatic brain injury
  o Tourette’s syndrome

• Cerebellar stimulation/pacing for any indication
• Occipital nerve stimulation for any indication
• gammaCore®
• Peripheral nerve stimulation

REFERENCES
1. Depression in adults: Overview of neuromodulation procedures. UpToDate.com/login [via subscription only]. Accessed April 19, 2021..

**APPROVAL HISTORY**


Subsequent endorsement date(s) and changes made:
- April 25, 2007: Reviewed and renewed, without changes
- April 30, 2008: The following CPT Codes were added to the MNG, 95972, 95973
- May 4, 2009: Reviewed and renewed, without changes
- May 2010: Reviewed at MSPAC, no changes
- December 2010: Reviewed at MSPAC, no changes
- April 11, 2012: Reviewed at IMPAC (Integrated Medical Policy Advisory Committee), changes made to criteria wording; trial requirement clarified
- September 11, 2013: Reviewed by IMPAC, criteria change to InterQual® SmartSheet™ with effective date of April 1, 2014. CPT code 63663 added.
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- January 1, 2015: Instructions for Tufts Health Plan – Network Health products included in this document.
- July 23, 2015: Reviewed by IMPAC, renewed without changes.
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- December 31, 2015: Coding updated. Per AMA CPT®, effective December 31, 2015 the following code(s) deleted: 95973.
- July 20, 2016: Reviewed by IMPAC, renewed without changes
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- October 10, 208: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- November 14, 2018: Reviewed by IMPAC. For effective date April 1, 2019, dorsal root ganglion stimulation is not covered and is added as MNG limitation.
- December 31, 2018: For effective date January 1, 2019 code description of CPT 95972 updated per AMA CPT®
• April 17, 2019: Reviewed at IMPAC. Effective April 17, 2019, positional adaptive spinal cord stimulation and burst-frequency spinal cord stimulation are not covered as these are considered investigational.

• October 16, 2019: Reviewed by IMPAC, renewed without changes

• January 15, 2020: Reviewed at IMPAC. Effective March 9, 2020 CPT 95972 requires prior authorization only when submitted with ICD10 codes applicable to SCS insertion diagnoses: failed back syndrome, CRPS and refractory angina

• February 19, 2020: Reviewed at IMPAC. Freedom Spinal Cord Stimulator (SCS) System added to limitations section

• October 21, 2020: Reviewed by IMPAC, renewed without changes

• 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 with Harvard Pilgrim Health Care, 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

**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.

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.