

**Policy: MP073**

**Section: Medical Benefit Policy**

**Subject: Deep Brain Stimulation**

### Applicable Lines of Business

<b>Commercial</b>	<b>X</b>	<b>CHIP</b>	<b>X</b>
<b>Medicare</b>	<b>X</b>	<b>ACA</b>	<b>X</b>
<b>Medicaid</b>	<b>X</b>		

**I. Policy:** Deep Brain Stimulation

**II. Purpose/Objective:**

To provide a policy of coverage regarding Deep Brain Stimulation

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**Medicaid Business Segment**

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

**DESCRIPTION:**

Unilateral or bilateral deep brain stimulation of the thalamus, or bilateral stimulation of the globus pallidus or sub-thalamic nucleus refers to a neurosurgical procedure where a device is implanted in the brain for the control of tremors in selected members who have been diagnosed with essential tremor or Parkinsonian tremor. The device consists of a pacemaker-like chest unit that transmits mild electrical pulses through a wire to a lead that is stereotactically implanted in the thalamus or selected surrounding structures. This procedure, being reversible, is an alternative to permanent neuroablative procedures such as thalamotomy and pallidotomy in patients with significant functional disability and who are refractory to maximized pharmacological management.

**INDICATIONS:**

- Essential tremor
- Parkinson’s disease tremor or complicated motor fluctuation
- Intractable primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia when used in accordance with the Humanitarian Device Exemption specifications of the U.S. Food and Drug Administration
- Medically refractory epilepsy

**CRITERIA FOR COVERAGE: Requires Prior Authorization by a Plan Medical Director or designee**

Note: This requirement only applies to initial placement, and not to revision(s) and replacement(s) after implantation.

Essential Tremor: unilateral or bilateral deep brain stimulation of the ventral intermediate (Vim) nucleus is considered medically necessary when all of the following criteria are met:

- Diagnosis of disabling essential tremor refractory to pharmacotherapy
- The tremor constitutes a significant functional disability as evidenced by a standardized scale (e.g., Fahn-Tolosa-Marin Clinical Tremor Rating Scale\*, TETRAS\*\*, or equivalent scale) or discussion of their ADL or iADL limitations with their physician.

\*<https://www.yumpu.com/en/document/view/11254127/fahn-tolosa-marin-tremor-rating-scale>

\*\* [https://www.bcm.edu/neurology/pdf/poster\\_other\\_TETRAS.pdf](https://www.bcm.edu/neurology/pdf/poster_other_TETRAS.pdf)

Parkinson’s Disease: unilateral or bilateral deep brain stimulation of the ventral intermediate thalamic nucleus, internal globus pallidus (GPi) or the subthalamic nucleus (STN) is considered medically necessary when all of the following criteria are met:

- History of clearly documented Parkinson’s disease, diagnosed using the UK Parkinson’s disease brain bank criteria that has responded to pharmacologic therapy in the past, **and**
- Having symptoms of parkinsonism for at least four years, and
- One of the following:
  - Disabling motor fluctuations despite optimized medical/pharmacologic therapy; or
  - Disabling tremor despite optimized medical/pharmacologic therapy.

Primary Dystonia unilateral or bilateral deep brain stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) is considered medically necessary when all of the following criteria are met:

- Chronic, intractable primary dystonia, including generalized and/or segmental dystonia, hemidystonia, or cervical dystonia (torticollis); and
- Member is 7 years of age or older; and
- Medical documentation that the condition is refractory to pharmacotherapy

Medically Refractory Epilepsy Deep brain stimulation of the anterior nucleus of thalamus is considered medically necessary using the Medtronic DBS System for Epilepsy when all of the following criteria are met:

- Member is 18 years of age or older; and
- Documentation of focal (partial-onset) seizures with or without secondary generalized seizures; and
- The member is currently averaging 6 or more focal (partial-onset) seizures per month with no more than 30 days between seizures with current antiepileptic drug regimen; and

- Is deemed to be medically refractory having tried and failed at least 3 antiepileptic drugs; and
- The member is not a candidate for, or has failed resective epilepsy surgery; and
- There is no evidence of a neurological disorder or condition likely to progress such as but not limited to: brain tumor, arteriovenous malformations (AVM) that are likely to progress; meningitis or abscess; or encephalitis.

**NOTE: Services related to component reimplantation or replacement in members previously approved for the implantation, or members having had the implantation prior to enrollment in the Plan, and who otherwise meet criteria for coverage, do not require prior authorization.**

**CONTRAINDICATIONS:**

- Independent diagnoses that could explain the failure to respond to medical treatment
- Mental impairment, moderate to severe cognitive impairment or uncontrolled depression
- Focal lesions of the basal ganglia (lacunae or space occupying lesion) or at the target site.
- Surgical risk is unacceptable due to comorbid conditions

**RESPONSIVE NEUROSTIMULATION:**

For criteria relate to responsive neurostimulation as a treatment for refractory treatment-resistant epilepsy, please see MP330 Responsive Neurostimulation

**EXCLUSIONS:**

The Plan does **NOT** provide coverage for Deep brain stimulation for control of tremor induced by any diagnosis other than those listed above because it is considered **experimental, investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies. The list of such diagnosis includes, but is not limited to:

- |   |                                   |
|---|-----------------------------------|
| • Trauma                                | • Multiple Sclerosis              |
| • Neurological Degenerative Disorders   | • Metabolic Disorders             |
| • Infectious Disease                    | • Drug Induced Movement Disorders |
| • Obsessive Compulsive Disorder         | • Tourette’s Syndrome             |
| • Tardive dyskinesia                    | • Neuropsychiatric conditions     |
| • Cerebral palsy                        | • Chronic pain                    |
| • Chronic Intractable Cluster Headaches |                                   |
| • Post-traumatic tremor                 |                                   |

**Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven services is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment**

**CODING ASSOCIATED WITH: Deep Brain Stimulation**

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements*

- 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 for stereotactic implantation of neurostimulator array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray) without use of intraoperative microelectrode recording; first array
- 61864 each additional array
- 61867 Twist drill, burr hole, craniotomy, or craniectomy for stereotactic implantation of neurostimulator array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus,

- periventricular, periaqueductal gray) with use of intraoperative microelectrode recording; first array
- 61868 each additional array
  - 61870 craniectomy for implantation of neurostimulator electrodes, cerebellar, cortical
  - 61880 Revision or removal of intracranial neurostimulator electrodes
  - 61885 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
  - 61886 with connection to two or more electrode arrays
  - 61888 Revision or removal of cranial neurostimulator pulse generator or receiver
  - 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)
  - 61891 Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)
  - 61892 Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed
  - 95961 Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizure or identify vital brain structures; initial hour of physician attendance
  - 95962 each additional hour of physician attendance (List separately in addition to code for primary procedure)
  - 95970 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and 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, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
  - 95971 simple brain, spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
  - 95972 complex brain, spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
  - 95974 Electronic analysis of implanted neurostimulator pulse generator
  - 95975 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 compliance measurements); complex cranial neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, each additional 30 minutes after first hour
  - 95978 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, w/ initial or subsequent programming; first hour
  - 95979 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, w/ initial or subsequent programming; each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
  - C1767 generator neurostimulator (implantable) non-rechargeable
  - C1778 lead, neurostimulator
  - C1787 patient programmer, neurostimulator
  - C1816 receiver and/or transmitter neurostimulator (implantable)
  - C1820 generator, neurostimulator (implantable), non high-frequency with rechargeable battery and charging system
  - C1822 generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
  - C1897 lead neurostimulator test kit (implantable)
  - L8679 implantable neurostimulator, pulse generator, any type
  - L8680 Implantable neurostimulator electrode, each
  - L8681 Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
  - L8682 implantable neurostimulator radiofrequency receiver
  - L8683 radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
  - L8685 implantable neurostimulator pulse generator, single array, rechargeable, includes extension
  - L8686 implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
  - L8687 implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
  - L8688 implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

**LINE OF BUSINESS:**

**Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.**

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This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 12/02

**Revised:** 1/04 (Coding, references); 1/06 (criteria, exclusions and references); 1/07; 2/12 (added indications, contraindication), 12/12 (added indications); 12/16 (revised criteria); 11/19 (add reference for responsive neurostimulation); 11/20 (add epilepsy indication)

**Reviewed:** 1/05, 1/08, 1/09, 2/10, 2/11, 12/13, 12/14, 12/15, 11/17, 11/18, 11/21, 11/22, 11/23

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