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MP.108 Deep Brain and Dorsal Column (Spinal Cord) Neurostimulators Policy

Maryland Physicians Care considers **Deep Brain and Dorsal Column (Spinal Cord) Neurostimulators** medically necessary for the following indications:

A. Deep Brain Neurostimulators (DBS) – ALL of the following:

1. The device is a Food and Drug Administration (FDA) approved device for DBS, or the device is being used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.
2. Other treatment modalities (pharmacological, surgical, physical, and/or psychological therapies) have been tried and failed or are unsuitable or contraindicated for the member.
3. The member has undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. Screening must include psychological (only for Parkinson's disease to rule out behavioral health diagnosis), and physical evaluations. *(Note: Refer to Limitation section)*
4. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications, and stimulator settings.
5. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the member are available.

Specific Coverage Criteria

Thalamic Ventralis Intermedius Nucleus (VIM) DBS, Unilateral or Bilateral is considered medically necessary:

1. For the treatment of:
   - Essential Tremor (ET) and/or Parkinson Tremor

   AND
2. When all of the following are met:
   - Diagnosis of ET is based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least two cardinal PD features (tremor, rigidity or bradykinesia) which is of a tremor-dominant form.
   - 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.

Subthalamic Nucleus (STN) or Globus Pallidus Interna (GPi) DBS, Unilateral or Bilateral is considered medically necessary:

1. For the treatment of Parkinson Disease (PD)
   AND
2. When all of the following are met:
   - Diagnosis of PD is based on the presence of at least two cardinal PD features (tremor, rigidity or bradykinesia).
   - Advanced idiopathic PD as determined by the use of Hoehn and Yahr stage, or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale.
   - L-dopa responsive with clearly defined "on" periods.
   - Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) are present despite optimal medical therapy.

B. Dorsal Column (Spinal Cord) Neurostimulators (DCS) for Chronic Intractable Pain – for ALL of the following:

1. The device is Food and Drug Administration (FDA) approved devices for DCS, or the device is used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DCS clinical trials.
2. The implantation of the stimulator is used only as a late resort (if not last resort) for members with chronic intractable pain.
3. Other treatment modalities (pharmacological, surgical, physical, and/or psychological therapies) have been tried and failed or are unsuitable or contraindicated for the member.
4. The member has undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation screening must include psychological and physical evaluation.
5. The member is willing and able to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.
6. A temporary stimulator trial has preceded permanent implantation and demonstrates significant pain reduction (50% or more).
   Note: The indications for a trial stimulator are the same as for permanent implantation, and trial period may be extended up to four weeks.
7. All the facilities, equipment, professional and support personnel required for the proper diagnosis, treatment training, and follow up of the member are available.

Specific Coverage Criteria

DCS is considered medically necessary for the **treatment of intractable pain** caused by any of the following:

1. Post-surgical or post traumatic nerve root injuries, including post laminectomy syndrome
2. Lumbosacral arachnoiditis that has not responded to medical management including physical therapy
   Note: Lumbosacral arachnoiditis is usually documented by the presence of high levels of protein in the cerebral spinal fluid (CSF) and/or by magnetic resonance imaging (MRI) or myelography
3. Complex regional pain syndrome I & II
4. Phantom limb syndrome that has not responded to medical management or injection therapy
5. End stage peripheral vascular disease when the member cannot undergo revascularization or when revascularization has failed to relieve painful symptoms and the pain has not responded to medical management
6. Post-herpetic neuralgia
7. Plexopathy
8. Intercostal neuralgia that has not responded to nerve blocks and medical management
9. Cauda equina injury
10. Incomplete spinal cord injury
11. Chronic intractable pain in a patient who is a poor surgical candidate due to co-morbidities and/or age

C. Deep Brain Neurostimulation for Cervical Dystonia for ALL of the following:

1. Must be 7 years of age or older;
2. Must have generalized primary dystonia;
3. Must be refractory to medical treatment, having been treated with at least two medications from two different groups at the maximum recommended dose for at least two months and are surgical candidates;
4. If treated by intrathecal Baclofen delivered by a pump, a switch to oral Baclofen is required to remove the pump;
5. Must have a minimum Burke-Fahn-Mardsen (BFM) score of 20 on optimal medical therapy; and
6. Adults must be mentally competent to consent for entrance into the protocol.

D. Responsive Neurostimulation (RNS) for the treatment of Epilepsy for ALL of the following:

1. Must be 18 years of age or older;

2. Must have frequent disabling partial onset seizures originating in one or two areas of the brain;
3. Epilepsy must be refractory to two or more well-tolerated antiepileptic medications;
4. Diagnostic testing should identify no more than two localized epileptogenic foci; and

Must be unable to have epilepsy surgery or who had resective surgery before and are still having seizures.

Limitations

Deep Brain Neurostimulators (DBS)

1. DBS is not reasonable and necessary and is not covered for ET or PD members 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 member's ability to benefit from DBS
   - Current psychosis, alcohol abuse or other drug abuse
   - Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder
   - Previous movement disorder surgery within the affected basal ganglion
   - Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation

Precautions:

- Members who undergo DBS implantation should not be exposed to diathermy (deep heat treatment including shortwave diathermy, microwave diathermy and ultrasound diathermy) or any type of MRI, which may adversely affect the DBS system or adversely affect the brain around the implanted electrodes.
- DBS should be performed with extreme caution in members with cardiac pacemakers or other electronically controlled implants, which may adversely affect or be affected by the DBS system

2. Physicians specializing in movement disorders must be involved in both patient selections and post-procedure care.

3. The neurosurgeon performing the procedure must be:
   a) Properly trained;
   b) Have experience performing stereotactic neurosurgical procedures, and surgical management of movement disorders, including DBS therapy;

c) Have experience performing stereotactic neurosurgical procedures

4. Hospitals medical centers need to have:
   a) Brain imaging equipment (MRI and/or CT) for pre-operative stereotactic localization and targeting of the surgical site(s);
   b) Operating rooms with all necessary equipment for stereotactic surgery; and;
   c) Support services necessary for care of patients undergoing this procedure and any potential complications arising intraoperatively or postoperatively
   d) Operative teams with training and experience with DBS systems, including knowledge of anatomical and neurophysiological characteristics for localizing the targeted nucleus, surgical and/or implantation techniques for the DBS system, and operational and functional characteristics of the device

Dorsal Column (Spinal Cord) Neurostimulators (DCS)
1. Electronic analysis services are limited to one every 30 days
2. Generally the dorsal column neurostimulation procedure is limited to neurosurgeons, orthopedic surgeons, and anesthesiologists specializing in pain management. Professional competency of the physician to perform DCS must be documented and available upon request.

Deep Brain Neurostimulation for Cervical Dystonia is not medically necessary when:
1. There is a history of lesioning surgery, including radiofrequency lesioning of deep nuclei (such as thalamus, pallidum or STN;
2. Patient has a functioning, effective deep brain nuclei (thalamus, pallidum, STN) stimulator;
3. The preoperative evaluation demonstrates patient is unable to tolerate surgery;
4. Patient has a coagulopathy demonstrated by an abnormal prothrombin time, activated partial thromboplastin time, or thrombocytopenia (platelet count less than 150,000 platelets/mm(3));
5. Patient has an acute or untreated viral, bacterial or fungal infection;
6. Patient had a previous surgery that involved placement of metal objects that could cause tissue damage or produce image artifacts;
7. Patient has another chronic neurologic disorder;
8. Patient is pregnant at the time of surgery;
9. Patient has epilepsy;
10. Patient does not have the proper support system for follow-up are at home.

Responsive Neurostimulation (RNS) – services are not medically necessary when:
1. The criteria above is not met;
2. When there are three or more specific seizure foci;

3. Presence of primary generalized epilepsy; or
4. Presence of rapidly progressive neurologic disorder.

Background

Deep brain stimulation (DBS) refers to high-frequency electrical stimulation of anatomic regions deep within the brain utilizing neurosurgically implanted electrodes. These DBS electrodes are stereotactically placed within targeted nuclei on one (unilateral) or both (bilateral) sides of the brain. There are currently three targets for DBS -- the thalamic ventralis intermedius nucleus (VIM), subthalamic nucleus (STN) and globus pallidus interna (GPi).

Essential tremor (ET) is a progressive, disabling tremor most often affecting the hands. ET may also affect the head, voice and legs. ET affects more than one million Americans and at least 1% of the adult population over the age of 40. Parkinson's disease (PD) is an age-related progressive neurodegenerative disorder involving the loss of dopaminergic cells in the substantia nigra of the midbrain. The disease is characterized by tremor, rigidity, bradykinesia and progressive postural instability.

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 patients with chronic pain, including chronic, refractory, neuropathic pain. SCS are made up of three components: leads/electrodes, a generator/power source, and a programmer/controller.

Hoehn and Yahr stages of Disability**:**

- Stage I - Unilateral involvement only, usually with minimal or no functional impairment.
- Stage II - Bilateral or midline involvement, without impairment of balance.
- Stage III - First sign of impaired righting reflexes, evident by unsteadiness as patient turns or demonstrated when patient is pushed from standing equilibrium with the feet together and eyes closed. Functionally, the patient is somewhat restricted but is capable of activities of daily living (ADL). Disability is mild to moderate.
- Stage IV - Fully developed severe disabling disease. The patient is still able to walk and stand unassisted but is markedly incapacitated.
- Stage V - Confinement to wheelchair unless aided.

The Unified Parkinson Disease Rating Scale (UPDRS) is a rating tool used to follow the longitudinal course of PD. Its three sections include:

1] Mentation, Behavior, Mood;
2] ADL;
3] Motor Sections

The scale allows for a total of 199 points, with a score of 0 indicating no disability.

Dystonia is a disorder causing involuntary muscle contractions leading to abnormal postures and movements. It can affect different parts of the body, varying from focal to general. The disorder can be classified into primary and secondary dystonia. Primary dystonia is thought to have a genetic contribution, while secondary dystonia is often due to lesions in the basal ganglia, a brain region responsible for motor control. The severity of dystonia varies greatly, with some individuals able to lead a relatively normal lifestyle, while others may require assistance with daily activities.

Responsive Neurostimulation (RNS) is a treatment of drug-resistant refractory focal Epilepsy where a small battery-powered device is implanted into the skull and is connected to leads which are placed in the area or areas of the brain where the patient's seizures originate. The neurostimulator monitors the brain's electrical activity. Once activity that could lead to a seizure is detected, it then delivers a pulse to electrical stimulation through the leads to stop the seizure before it begins. Seizures in patients treated with RNS and medication may be better controlled than patients treated with medication alone. As no brain tissue is removed this method of treatment poses less risk than other surgical treatments and is reversible as the implant can be removed at any time.

Codes

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
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 (thalamus, gobus pallidus, Subthalamic nucleus, periventricular, periaqueductal gray) without use of intraoperative microelectrode recording: 1st array

61864	Twist drill, burr hole craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (thalamus, gobus 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 (thalamus, gobus pallidus, Subthalamic nucleus, periventricular, periaqueductal gray) with use of intraoperative microelectrode recording: 1st array
61868	Twist drill, burr hole craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (thalamus, gobus pallidus, Subthalamic nucleus, periventricular, periaqueductal gray) with use of intraoperative microelectrode recording: each additional array
61880	Revision or removal of intracranial neurostimulator electrodes
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 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
Dorsal Column/Spinal Stimulators	
63650	Percutaneous implantation of neurostimulator electrode, epidural
63655	Laminectomy for implantable neurostimulator electrodes, plate/paddle, epidural

63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
Other	
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter (implantable)
C1820	Generator, neurostimulator (implantable) with rechargeable battery and charging system
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system
C1827	Generator, neurostimulator (implantable), nonrechargeable, with implantable stimulation lead and external paired stimulation controller
C1897	Lead, neurostimulator test kit (implantable)
L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
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 r 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

L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only
Electronic Analysis (Allow only 1 every 30 days)	
95970	Electronic analysis of implanted neurostimulator pulse generator system, simple or complex brain, spinal cord, or peripheral neurostimulator pulse generator/transmitter without programming
95971	Electronic analysis of implanted neurostimulator pulse generator system, simple or complex brain, spinal cord, or peripheral neurostimulator pulse generator/transmitter with intraoperative or subsequent programming
95972	Electronic analysis of implanted neurostimulator pulse generator system, simple or complex brain, spinal cord, or peripheral neurostimulator pulse generator/transmitter with intraoperative or subsequent programming, first hour
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostim
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostim
ICD-10 Codes for the following Deep Brain Stimulator CPT codes: 61863, 61864, 61867, 61868:	
G20	Parkinson's disease
G21.8	Other secondary parkinsonism
G24.1	Genetic torsion dystonia
G24.3	Spasmodic torticollis
G24.8	Other dystonia
G25.0	Essential tremor
G25.2	Other specified forms of tremor
ICD-10 Codes for the following Dorsal Column Neurostimulator CPT codes: 63650, 63655, and 63685:	
B02.22	Postherpetic trigeminal neuralgia

B02.23	Postherpetic polyneuropathy
B02.29	Other postherpetic nervous system involvement
G03	Meningitis due to other and unspecified causes
G03.0-G03.9	Meningitis due to other and unspecified causes
G54.6	Phantom limb syndrome with pain
G54.7	Phantom limb syndrome without pain
G54.8	Other nerve root and plexus disorders
G56	Mononeuropathies of upper limb
G56.00-G56.93	Mononeuropathies of upper limb
G57	Mononeuropathies of lower limb
G57.00-G57.93	Mononeuropathies of lower limb
G60	Hereditary and idiopathic neuropathy
G60.0-G60.9	Hereditary and idiopathic neuropathy
G90.5	Complex regional pain syndrome I (CRPS I)
G90.50-G90.529	Complex regional pain syndrome I (CRPS I)
I73	Other peripheral vascular diseases
I73.00-I73.9	Other peripheral vascular diseases
M51.04	Intervertebral disc disorders with myelopathy, thoracic region
M51.05	Intervertebral disc disorders with myelopathy, thoracolumbar region
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M51.24	Other intervertebral disc displacement, thoracic region
M51.25	Other intervertebral disc displacement, thoracolumbar region
M51.26	Other intervertebral disc displacement, lumbar region
M51.27	Other intervertebral disc displacement, lumbosacral region
M51.44	Schmorl's nodes, thoracic region
M51.45	Schmorl's nodes, thoracolumbar region

M51.46	Schmorl's nodes, lumbar region
M51.47	Schmorl's nodes, lumbosacral region
M51.9	Unspecified thoracic, thoracolumbar and lumbosacral intervertebral disc disorder
M54.12	Radiculopathy, cervical region
M54.13	Radiculopathy, cervicothoracic region
M96.1	Postlaminectomy syndrome, not elsewhere classified
S22.0	Fracture of thoracic vertebra
S22.000A-S22.089S	Fracture of thoracic vertebra
S24.1	Other and unspecified injuries of thoracic spinal cord
S24.101A-S24.109S	Other and unspecified injuries of thoracic spinal cord
S32.0	Fracture of lumbar vertebra
S32.000A-S32.059S	Fracture of lumbar vertebra
S33.1	Subluxation and dislocation of lumbar vertebra
S33.100A-S33.141S	Subluxation and dislocation of lumbar vertebra
S34.1	Other and unspecified injury of lumbar and sacral spinal cord
S34.101A-S34.139S	Other and unspecified injury of lumbar and sacral spinal cord
S34.3	Injury of cauda equina

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