Health Plans

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Medicare Advantage **X Commercial**

Deep Brain, Dorsal Column (Spinal Cord), and Peripheral Neurostimulators Policy

I. Purpose

Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for Deep Brain, Dorsal Column (Spinal Cord), and Peripheral Neurostimulators.

II. Scope

This policy applies to all Utilization Management staff having decision- making responsibilities where authorization is required for Fully Insured plans.

III. Exceptions

A. Deep Brain Neurostimulators (DBS)

1. DBS is not reasonable and necessary and is not covered for Essential Tremor or Parkinson Disease members with **any of the following:**

a. Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes
b. Cognitive impairment, dementia, or depression, which would be worsened by or would interfere with the member's ability to benefit from DBS
c. Current psychosis, alcohol abuse or other drug abuse
d. Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder
e. Previous movement disorder surgery within the affected basal ganglion
f. Significant medical, surgical, neurologic, or orthopedic co-morbidities contraindicating DBS surgery or stimulation

2. DBS will need careful review for the following:

a. Patients who will require MRI or diathermy post-operatively
b. Use of extreme caution in patients with cardiac pacemakers or other electronically controlled implants which may be affected by the DBS system

B. 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.
3. Dorsal Column (Spinal Cord) Neurostimulator (DCS) Trial indications are the same as for permanent implantation and the trial period may extend up to 4 weeks.

C. Peripheral nerve stimulation devices are considered investigational and not medically necessary for all indications including, but not limited to, treatment of acute and chronic pain.

IV. Definitions

Deep brain stimulation (DBS) refers to high-frequency electrical stimulation of anatomic regions deep within the brain utilizing neurosurgical 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).

Dorsal Column (Spinal Cord) Neurostimulation- the surgical implantation of neurostimulator electrodes within the dura mater or epidural space

Electrical Nerve Stimulators are devices used to treat intractable pain. They can either be peripheral or central nervous system stimulators.

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.

V. Policy Statements

IU Health Plans considers Deep Brain and Dorsal Column (Spinal Cord) Neurostimulators medically necessary for **one of the following** indications:

A. Deep Brain Neurostimulators (DBS**)** are covered when **all of the following** criteria is met**:**

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 themember.
3. The member has undergone careful screening, evaluation, and diagnosis to include ALL of the following:
   a. psychological evaluations to include screening for suicidal tendencies.
   b. No coagulopathy
   c. No contraindication to permanent hardware implantation (examples but not limited to:chronic infection, immunocompromised)
   d. No significant cognitive impairment
   e. No intracranial pathology or imaging studies that would contraindicate or complicate Deep Brain Stimulation.
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.
6. Physicians specializing in movement disorders must be involved in both patient selections and post-procedure care.
7. The neurosurgeon performing the procedure must meet **all of the following** criteria:
   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
8. Hospitals medical centers must meet **all of the following** criteria:
   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
   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, includingknowledge 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
9. Must meet criteria for **one of the following** specific procedures:
   a. Thalamic Ventralis Intermedius Nucleus (VIM) DBS, Unilateral or Bilateral is considered medically necessary when **all of the following** criteria is met:

i. Treatment of Essential Tremor (ET) and/or Parkinson Tremor
ii. 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.
iii. 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.

b. Subthalamic Nucleus (STN) or Globus Pallidus Interna (GPi) DBS, Unilateral or Bilateral is considered medically necessary when **all of the following** criteria is met:
i. For the treatment of Parkinson Disease (PD)
ii. Diagnosis of PD is based on the presence of at least two cardinal PD features (tremor, rigidity or bradykinesia).
iii. 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.
iv. L-dopa responsive with clearly defined "on" periods.
v. 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 is covered when **all of the following** criteria are met**:**
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 for at least 6 months or are unsuitable or are 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 including screening for any coagulopathy, thrombocytopenia, or chronic infection.
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 for 5-7 days has preceded permanent implantation and demonstrates significant pain reduction (50% or more).
7. All the facilities, equipment, professional and support personnel required for the proper diagnosis, treatment training, and follow up of the member are available.
8. No history of drug abuse and urine drug screen from within the past 3 months resulted appropriately.
9. DCS is considered medically necessary for the treatment of intractable pain caused by **one of the following**:
   a. Post-surgical or post traumatic nerve root injuries, including post laminectomy syndrome
   b. 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)

c. Complex regional pain syndrome I & II
d. Phantom limb syndrome that has not responded to medical management or injection therapy
e. 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
f. Post-herpetic neuralgia
g. Plexopathy
h. Intercostal neuralgia that has not responded to nerve blocks and medical management
i. Cauda equina injury
j. Incomplete spinal cord injury
k. Chronic intractable pain in a patient who is a poor surgical candidate due to co-morbidities and/or age

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
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
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	Under Neurostimulators (Intracranial) Procedures on the Skull, Meninges, and Brain
62321	Under Injection, Drainage, or Aspiration Procedures on the Spine and Spinal Cord
62323	Under Injection, Drainage, or Aspiration Procedures on the Spine and Spinal Cord

62325	Under Injection, Drainage, or Aspiration Procedures on the Spine and Spinal Cord, imaging guidance
63650	Under neurostimulators (Spinal) Procedures
63655	Under neurostimulators (Spinal) Procedures, permanent electrode in epidural space
63661	Under neurostimulators (Spinal) Procedures- removal of electrodes
63662	Under neurostimulators (Spinal) Procedures, removal plates/paddles
63663	Under neurostimulators (Spinal) Procedures, revise/replace permanent electrode array
63664	Under neurostimulators (Spinal) Procedures, revise/replace plates/paddles
63685	Under neurostimulators (Spinal) Procedures, insert or replace pulse generator
63688	Under neurostimulators (Spinal) Procedures. Revises or removes previously placed pulse generator or receiver
95961	Under Other EEG Testing Procedures- maps brain surface by placing and stimulating electrodes
95962	Under Other EEG Testing Procedures-additional hour brain surface mapping
95970	Under Neurostimulators Analysis- Programming Procedures
95983	Under Neurostimulators Analysis- Programming Procedures- programming adjustments
95984	Under Neurostimulators Analysis- Programming Procedures- face to face programming adjustments
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, direct or inductive coupling
Other	
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter (implantable)
C1820	Generator, neurostimulator (implantable) with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system

C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
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, 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
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
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
95974	Electronic analysis of implanted neurostimulator pulse generator system, complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming with/without nerve interface testing, 1st hour

VI. Procedures

None

VII. References/Citations

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8. Sdrulla, A. D., Guan, Y., & Raja, S. N. (2018). Spinal Cord Stimulation: Clinical Efficacy and Potential Mechanisms. *Pain practice: the official journal of World Institute of Pain*, *18*(8),1048–1067. Spinal Cord Stimulation: Clinical Efficacy and Potential Mechanisms - Sdrulla - 2018 - Pain Practice - Wiley Online Library

VIII. Forms/Appendices

None

IX. Responsibility

Medical Director