GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Various forms of electrical stimulation have been investigated as an alternative to permanent neuroablative procedures, such as thalamotomy and pallidotomy for neuroelectrical conditions. The technique using deep brain stimulation (DBS) has been most thoroughly investigated as an alternative to thalamotomy for unilateral control of essential tremor, and tremor associated with Parkinson's disease (PD). DBS has also been investigated in individuals with primary dystonia, defined as a neurological movement disorder characterized by involuntary muscle contractions, which force certain parts of the body into abnormal, contorted and painful movements or postures and which is unrelated to any other neurological condition. Treatment options for dystonia include oral or injectable medications (i.e., botulinum toxin) and destructive surgical or neurosurgical interventions (i.e., thalamotomies or pallidotomies) when conservative therapies fail.

Deep brain stimulation involves the stereotactic placement of an electrode into the brain (i.e., thalamus, globus pallidus, or subthalamic nucleus). The electrode is initially attached to a temporary transcutaneous cable for short-term stimulation to validate treatment effectiveness. Several days later, the individual returns to surgery for permanent subcutaneous implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator. The electrode is typically implanted unilaterally on the side corresponding to the most severe symptoms. However, the use of bilateral stimulation using two electrode arrays has also been investigated in individuals with bilateral, severe symptoms.

After implantation, noninvasive programming of the neurostimulator can be adjusted to the individual's symptoms. This feature may be important for individuals with PD, whose disease may progress over time, requiring different neurostimulation parameters. Setting the optimal neurostimulation parameters may involve the balance between optimal symptom control and appearance of side effects of neurostimulation, such as dysarthria, disequilibrium, or involuntary movements.

Cortical stimulation is a newer technology proposed for the treatment of epilepsy. Currently the only device available for this type of treatment is the RNS System (NeuroPace, Inc., Mountain View, CA). The RNS System involves implantation of electrodes onto the surface the brain near areas associated with seizure activity. Those electrodes are then attached to a control/generator unit which is also implanted in the head. The control unit monitors and records electrical activity of the brain and provides electrical stimulation when needed. Following a trial period, the initial brain activity record is evaluated by a doctor. The record is used to identify the individual's unique pre-seizure electrical brain activity patterns and to set the RNS device to recognize and react to those patterns. Once the recognition parameters are set, the device monitors brain activity for the pre-set patterns of electrical activity. If those patterns are detected the device activates to provide stimulation through the electrodes with the goal of preventing a seizure.

Cerebral stimulation or pacing, also referred to as motor cortex stimulation (MCS) or extradural motor cortex stimulation (EMCS), is primarily proposed for relief of refractory neuropathic pain and involves implantation of epidural electrodes in the cerebral cortex. It is a similar technique to DBS, but works in the cerebellar portion of the brain. At this time there is little information about the use of this technology in humans.

POLICY
Deep brain stimulation does not require prior authorization.
Cortical stimulation does not require prior authorization.
Cerebellar stimulation is non-covered.
Unilateral or bilateral deep brain stimulators (e.g., stimulation of the ventral intermediate thalamic nucleus, globus pallidus, and subthalamic nucleus) are medically necessary durable medical equipment (DME) for the treatment of intractable tremors as a consequence of Parkinson's disease or essential tremor when ALL of the following criteria are met:

- Member does not have dementia, severe depression, or cerebral atrophy
- Member does not have other independent diagnoses that could explain the failure to respond to medical treatment, and
- Member suffers from disabling upper extremity essential tremor that is not responding satisfactorily to drug therapy or suffers from a disabling tremor of idiopathic Parkinson's disease that is refractory to pharmacotherapy, and
- There is no focal lesion of the basal ganglia (e.g., a space occupying lesion or lacunae) at the target site that would negate the result of thalamic stimulation, and
- There is sufficient residual motor function in the upper extremity so that it is reasonable to expect an improvement following the surgery.

Unilateral or bilateral deep brain stimulators (e.g., stimulation of the globus pallidus and subthalamic nucleus) are medically necessary DME for the treatment of severe, refractory motor complications of Parkinson's disease when ALL of the following criteria are met:

- A minimal score of 30 points on the motor portion of the United Parkinson's Disease Rating Scale (UPDRS) when the member has been off medication for about 12 hours (scores on this scale range from 0 to 108; higher values indicate greater severity of symptoms); and
- Member does not have dementia, severe depression, or cerebral atrophy
- Member is levodopa responsive with clearly defined “on” periods; and
- Motor complications that can not be managed with medication; and
- Presence of at least 2 major symptoms of Parkinsonism (e.g., tremor, rigidity, and bradykinesia).

Unilateral or bilateral deep brain stimulators (e.g., stimulation of the globus pallidus and subthalamic nucleus) are medically necessary DME for the treatment of persons 7 years of age or older with intractable primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia.

DBS for tremors from other causes such as trauma, multiple sclerosis (MS), degenerative disorders, metabolic disorders, infectious diseases, and drug-induced movement disorders are experimental and investigational because DBS has not been shown to be effective for treating tremors due to these other causes.

DBS is experimental and investigational for the following indications (not an all inclusive list), because there is insufficient evidence to support its effectiveness for these indications.

- Addiction
- Alzheimer's disease
- Anorexia nervosa
- Autism spectrum disorder
- Blepharospasm
- Cerebral palsy
- Chronic cluster headache
- Chronic pain syndrome including complex regional pain syndrome/reflex sympathetic dystrophy
- Chronic vegetative state
- Depression
- Epilepsy
- Explosive aggressive behavior
- Head or voice tremor
- Huntington's disease
- Minimally conscious state
- Obesity
- Obsessive-compulsive disorder
- Orthostatic tremor
- Parkinson's disease-related camptocormia, dysarthria/speech deficits, and gait disorders (e.g., gait instability and freezing of gait)
• Post-traumatic tremor
• Self-injurious behavior
• Substance use disorders
• Tourette syndrome
• Traumatic brain injury

CORTICAL STIMULATION (61850-61864, 61880-61888, L8679, L8681, L8686, L8688)
Cortical stimulation is medically necessary when ALL of the following criteria are met:
• Member is 18 years of age or older
• Member has partial onset seizures
• Seizures are refractory to two or more antiepileptic medications
• Experiencing an average of three or more disabling seizures (e.g., motor partial seizures, complex partial
  and/or secondarily generalized seizures) per month over the three most recent months
• Diagnostic testing confirms localized seizure onset to one or two foci
• Member is not a candidate for focal resection epilepsy surgery
• Member is not a candidate for vagus nerve stimulation

CEREBELLAR STIMULATION (61850, 61860, 61880-61888, L8679-L8688)
The use of cerebellar stimulation/pacing is considered investigational and not medically necessary.

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria
that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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>61864</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; each additional array (List separately in addition to primary procedure)</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>61868</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; each additional array (List separately in addition to primary procedure)</td>
</tr>
<tr>
<td>61880</td>
<td>Revision or removal of intracranial neurostimulator electrodes</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 two or more electrode arrays</td>
</tr>
<tr>
<td>61888</td>
<td>Revision or removal of cranial neurostimulator pulse generator or receiver</td>
</tr>
</tbody>
</table>

HCPCS CODES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
</tr>
<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
</tr>
</tbody>
</table>

TAWG REVIEW DATES: 09/22/2017

REVISION HISTORY EXPLANATION
09/22/17: Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release
and Code Sets
Industry Standard Review
Hayes, Inc.