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| **Department of Origin:**<br>Integrated Healthcare Services | **Effective Date:**<br>03/05/24 |
| **Approved by:**<br>Medical Policy Quality Management Subcommittee | **Date Approved:**<br>03/05/24 |
| **Clinical Policy Document:**<br>Neurostimulation, Deep Brain and Cortical Brain (Responsive Cortical) | **Replaces Effective Clinical Policy Dated:**<br>03/07/23 |
| **Reference #:**<br>MC/I009 | **Page:**<br>1 of 12 |

**PURPOSE:**
The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

**POLICY:**
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

**GUIDELINES:**
Medical Necessity Criteria – Requests for deep brain stimulation (DBS) or cortical brain (Responsive Cortical) stimulation - Must satisfy any of the following: I or II

I. Deep brain stimulation - must satisfy any of the following: A or B

A. Initial placement - must satisfy any of the following: 1 - 4
1. *Chronic,* medically intractable limb tremor in essential tremor (ET) or severe disabling tremor of idiopathic Parkinson's disease (unilateral or bilateral DBS of the ventral intermediate [VIM] thalamic nucleus using the Activa® Tremor Control System ) - must satisfy both of the following: a and b
   a. *Tremor* causes significant impairment in *activities of daily living*; and
   b. Failure of pharmacotherapy (such as, but not limited to, propranolol and primidone).

2. *Chronic*, medically intractable primary dystonia (unilateral or bilateral DBS of the subthalamic nucleus or globus pallidus using the Activa® Dystonia Control System) when used in accordance with the Humanitarian Device Exemption (HDE) specifications of the FDA - must satisfy both of the following: a and b
   a. The member is 7 years of age or older; and
   b. Failure of pharmacotherapy for motor complications or chemodenervation with botulinum toxin.

3. Refractory motor complications of Parkinson's disease (PD) (unilateral or bilateral DBS of the subthalamic nucleus or globus pallidus using the Activa® Parkinson's Control Therapy System or Vercise/ Vercise Genus Deep Brain Stimulation System - must satisfy all of the following: a - e
   a. Presence of at least 2 major symptoms of Parkinson's disease (such as, but not limited to, *tremor*, rigidity, and bradykinesia), resulting in significant impairment of *activities of daily living*; and
   b. Failure of pharmacotherapy for motor complications; and
   c. Minimal score of 25 points on the motor portion (Section III) of the *Unified Parkinson's Disease Rating Scale (UPDRS)* (see Attachment A) when the member has been off medications for at least 12 hours; and

   [Note: Other comparable rating scales may be appropriate and will be assessed on a case-by-case basis]

d. Levodopa-responsive; and
e. Absence of severe dementia, severe depression, cerebral atrophy, and advanced (*Hoehn and Yahr Stage V*) Parkinson's disease.

4. Partial-onset seizures (bilateral stimulation of the anterior nucleus of the thalamus using the DBS System for Epilepsy) - must satisfy the following: a - d
   a. Member is at least 18 years of age; and
   b. History of partial-onset seizures with or without secondary generalization to tonic-clonic activity; and
   c. Seizures are refractory to three or more antiepileptic medications; and
   d. Member is experiencing an average of 6 or more seizures per month, over the most recent three months (with no more than 30 days between seizures).

[Note: If device implantation is covered, intraoperative functional cortical and subcortical mapping is also covered (CPTs 95961/95962)]

B. Replacement or revision of a deep brain stimulator generator/battery, lead or electrode, or patient programmer – must satisfy the following: 1, and 2 or 3, as applicable
   1. The indication for initial placement was for any of the following: a - d
      a. *Chronic*, medically intractable limb tremor in *essential tremor (ET)* or severe disabling tremor of idiopathic Parkinson's disease (unilateral or bilateral DBS of the ventral intermediate [VIM] thalamic nucleus using the Activa® Tremor Control System); or
      b. *Chronic*, medically intractable primary dystonia (unilateral or bilateral DBS of the subthalamic nucleus or globus pallidus using the Activa® Dystonia Control System) when used in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA); or
      c. Refractory motor complications of Parkinson's disease (PD) (unilateral or bilateral DBS of the subthalamic nucleus or globus pallidus using the Activa® Parkinson's Control Therapy System); or
      d. Refractory partial-onset seizures (bilateral stimulation of the anterior nucleus of the thalamus using the DBS System for Epilepsy).

   2. Request is for replacement of the existing generator/battery or patient programmer – must satisfy any of the following: a - b
      a. The battery life is less than 1 year; or
      b. The device must be *malfunctioning* and no longer under warranty; or

   3. Request is for replacement and/or revision of lead/electrode due to migration and/or no longer functioning properly is considered medically necessary.

II. Cortical (Responsive Cortical) neurostimulation (eg, NeuroPace RNS® System) – must satisfy any of the following: A or B

A. Initial placement - must satisfy all of the following: 1 - 7
   1. Member is at least 18 years of age; and

   2. History of partial-onset seizures; and

3. Seizures are refractory to two or more antiepileptic medications; and

4. Member is experiencing an average of 3 or more disabling seizures (eg, motor partial seizures, complex partial seizures and/or secondary generalized) per month, over the most recent three months; and

5. Diagnostic testing confirms localized seizures with no more than two epileptogenic regions; and

6. Member is not a candidate for focal resection epilepsy surgery; and

7. Member is not a candidate for vagus nerve stimulation.

B. Replacement or revision of cortical (Responsive Cortical) neurostimulation generator/battery, lead or electrode, or patient programmer – must satisfy: 1, and 2 or 3, as applicable
   1. The indication for initial placement was for refractory partial-onset seizures; and

   2. Request is for replacement of the existing generator/battery or patient programmer - must satisfy one of the following: a - b
      a. The battery life is less than 1 year; or
      b. The device is *malfunctioning* and no longer under warranty.

   3. Request is for replacement and/or revision of lead/electrode due to migration and/or no longer functioning properly is considered medically necessary.

**EXCLUSIONS (not limited to):**
Refer to member's Certificate of Coverage or Summary Plan Description.

The following are considered investigative for deep brain stimulation (see Investigative List): I - XXIII
[Note: Does not apply to cortical brain (Responsive Cortical) stimulation]

I. Addiction

II. Alzheimer's disease

III. Anorexia nervosa

IV. Blepharospasm

V. Cerebral palsy

VI. Chronic pain syndrome including complex regional pain syndrome/reflex sympathetic dystrophy

VII. Chronic vegetative state

VIII. Cluster headaches

IX. Cortical-basal ganglionic degeneration or other degenerative disorders

X. Depression

XI. Head or voice tremor

XII. Huntington's disease

XIII. Infectious diseases

XIV. Metabolic disorders

XV. Minimally conscious state

XVI. Multiple sclerosis (MS)

XVII. Obesity

XVIII. Obsessive compulsive disorder (OCD)

XIX. Parkinson's disease-related dysarthria/speech deficits

XX. Post-traumatic dyskinesia or other trauma

XXI. Progressive supranuclear palsy

XXII. Tardive dyskinesia or other drug-induced movement disorders

XXIII. Tourette syndrome

**DEFINITIONS:**

Activa® Tremor Control System (Medtronic):
Approved by the FDA under the premarket approval process (PMA) for "unilateral thalamic stimulation for the suppression of tremor in the upper extremity in patients who are diagnosed with essential tremor or Parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability".

Activa® Parkinson's Control Therapy System (Medtronic):
Approved by the FDA under the PMA process for "bilateral stimulation of the internal globus pallidus (GPi) or the subthalmic nucleus (STN) for adjunctive therapy in reducing some of the symptoms of advanced, Levodopa-responsive Parkinson's disease that are not adequately controlled with medication".

Activa® Dystonia Control System (Medtronic):
Approved by the FDA under the Humanitarian Device Exemption (HDE) process. This device was approved for unilateral or bilateral stimulation of the GPi or STN to aid in the management of chronic, intractable (i.e., drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (ie, torticollis) in patients seven years of age and older.

Activities of Daily Living (ADL):
Eating, toileting, transferring, bathing, dressing, walking, and continence

Chronic:
Greater than or equal to 6 months in duration

Dystonia:
A movement disorder wherein the tissue/muscle contracts uncontrollably in a disordered state. The following are types of dystonia:

- Cervical dystonia (a.k.a. spasmodic torticollis): neck muscles contract involuntarily
- General dystonia: affects most body parts, if not all
- Focal dystonia: affects a specific body part
- Hemidystonia: involuntary, sustained posturing of only one side of the body
- Multifocal dystonia: affects multiple body parts that are not related in function
- Segmental dystonia: affect two adjoining parts of the body

Essential tremor:
A progressive neurological disorder that is the most common cause of postural or action *tremor* that often affects the arms, but may also affect other body parts

DBS System for Epilepsy (Medtronic):
Approved by the FDA under the premarket approval process (PMA) for epilepsy characterized by partial onset seizures and have failed at least three anti-epileptic medications

Hoehn and Yahr Stage V:
A stage in the Parkinson's disease progression characterized by the following:

- Cachectic stage
- Invalidism complete
- Cannot stand or walk
- Requires constant nursing care

Malfunctioning:
The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

NeuroPace RNS® System (NeuroPace):
Approved by the FDA under the PMA process as "an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial-onset seizures who have undergone diagnostic testing that localized no more than 2 epileptogenic foci, are refractory to two or more antiepileptic medications, and currently have frequent and disabling seizures (motor partial seizures, complex partial seizures and / or secondarily generalized seizures). The RNS® System has demonstrated safety and effectiveness in patients who average 3 or more disabling seizures per month over the three most recent months (with no month with fewer than two seizures), and has not been evaluated in patients with less frequent seizures."

Parkinson's disease:
A gradually progressing motor disorder caused by the loss of brain cells that produce dopamine.

Tremor:
Rhythmic and oscillatory movement of a body part consisting of a constant frequency and variable amplitude

Unified Parkinson's Disease Rating Scale (see Attachment A):
Rating tool to follow the longitudinal course of Parkinson's disease

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Prior Authorization: Yes, per network provider agreement.

**CODING:**

CPT® Deep Brain Stimulation

61863 Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalmic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording, first array

61864 each additional array

61867 Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalmic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording, first array

61868 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 2 or more electrode arrays

CPT® Cortical Brain Stimulation

61850 Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical

61860 Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical

61886 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays

61880 Revision or removal of intracranial neurostimulator electrodes

61888 Revision or removal of cranial neurostimulator pulse generator or receiver



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| **Revised Date:** 12/19/12, 01/10/13, 01/14/15, 02/03/16, 01/17/17, 01/09/20, 03/20/20, 03/04/21, 09/27/21 |

**Attachment A**

**Unified Parkinson's Disease Rating Scale, Section III (Motor Exam)**

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|---|---|
| Speech | 0-normal<br>1-slight loss of expression, diction, volume<br>2-monotone, slurred but understandable, mod. impaired<br>3-marked impairment, difficult to understand<br>4-unintelligible |
| Facial Expression | 0-normal<br>1-slight hypomymia, could be poker face<br>2-slight but definite abnormal diminution in expression<br>3-mod. hypomimia, lips parted some of time<br>4-masked or fixed face, lips parted 1/4 of inch or more with complete loss of expression |
| Tremor at Rest | Face, Right Upper Extremity (RUE), Left Upper Extremity (LUE), Right Lower Extremity (RLE), and Left Lower Extremity (LLE) – score separately:<br>0-absent<br>1-slight and infrequent<br>2-mild and present most of time<br>3-moderate and present most of time<br>4-marked and present most of time |
| Action or Postural Tremor | RUE and LUE – score separately:<br>0-absent<br>1-slight, present with action<br>2-moderate, present with action<br>3-moderate present with action and posture holding<br>4-marked, interferes with feeding |
| Rigidity | Neck, RUE, LUE, RLE, and LLE – score separately:<br>0-absent<br>1-slight or only with activation<br>2-mild/moderate<br>3-marked, full range of motion<br>4-severe |
| Finger Taps | Right and Left – score separately:<br>0-normal<br>1-mild slowing, and/or reduction in amplitude<br>2-moderate impaired. Definite and early fatiguing, may have occasional arrests<br>3-severely impaired. Frequent hesitations and arrests.<br>4-can barely perform |
| Hand Movements (open and close hands in rapid succession) | Right and Left – score separately:<br>0-normal<br>1-mild slowing, and/or reduction in amplitude<br>2-moderate impaired. Definite and early fatiguing, may have occasional arrests<br>3-severely impaired. Frequent hesitations and arrests<br>4-can barely perform |

Unified Parkinson's Disease Rating Scale, Section III (continued)

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|---|---|
| Rapid Alternating Movements (pronate and supinate hands) | Right and Left – score separately:<br>0-normal<br>1-mild slowing, and/or reduction in amplitude<br>2-moderate impaired. Definite and early fatiguing, may have occasional arrests<br>3-severely impaired. Frequent hesitations and arrests.<br>4-can barely perform |
| Leg Agility (tap heel on ground, amplitude should be 3 inches) | Right and Left – score separately:<br>0-normal<br>1-mild slowing, and/or reduction in amplitude<br>2-moderate impaired. Definite and early fatiguing, may have occasional arrests<br>3-severely impaired. Frequent hesitations and arrests.<br>4-can barely perform |
| Arising From Chair (patient arises with arms folded across chest) | 0-normal<br>1-slow, may need more than one attempt<br>2-pushes self up from arms or seat<br>3-tends to fall back, may need multiple tries but can arise without assistance<br>4-unable to arise without help |
| Posture | 0-normal erect<br>1-slightly stooped, could be normal for older person<br>2-definitely abnormal, mod. stooped, may lean to one side<br>3-severely stooped with kyphosis<br>4-marked flexion with extreme abnormality of posture |
| Gait | 0-normal<br>1-walks slowly, may shuffle with short steps, no festination or propulsion<br>2-walks with difficulty, little or no assistance, some festination, short steps or propulsion<br>3-severe disturbance, frequent assistance<br>4-cannot walk |
| Postural Stability (retropulsion test) | 0-normal<br>1-recovers unaided<br>2-would fall if not caught<br>3-falls spontaneously<br>4-unable to stand |
| Body Bradykinesia/ Hypokinesia | 0-none<br>1-minimal slowness, could be normal, deliberate character<br>2-mild slowness and poverty of movement, definitely abnormal, or decreased amplitude of movement<br>3-moderate slowness, poverty, or small amplitude<br>4-marked slowness, poverty, or amplitude |

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**Attachment B**

Image of Deep Brain Stimulation
Retrieved from the National Institute of Mental Health

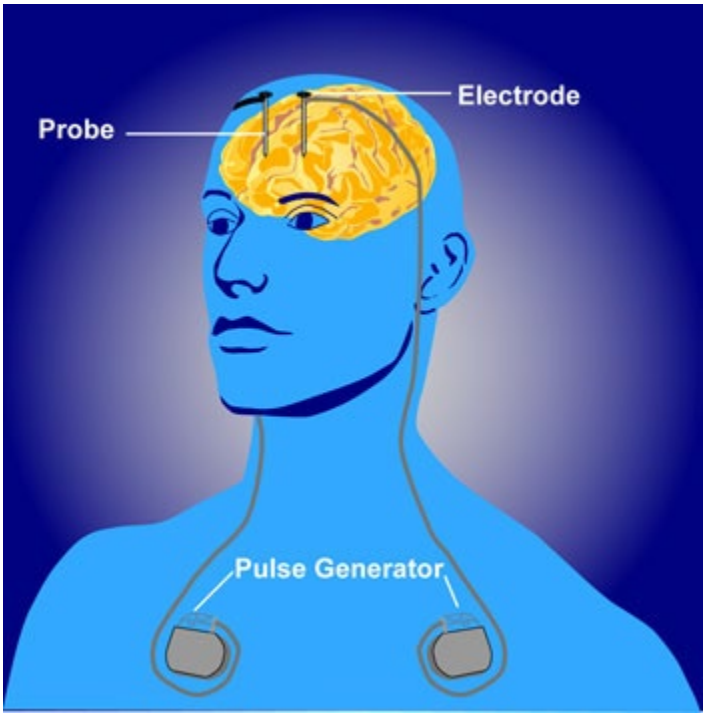
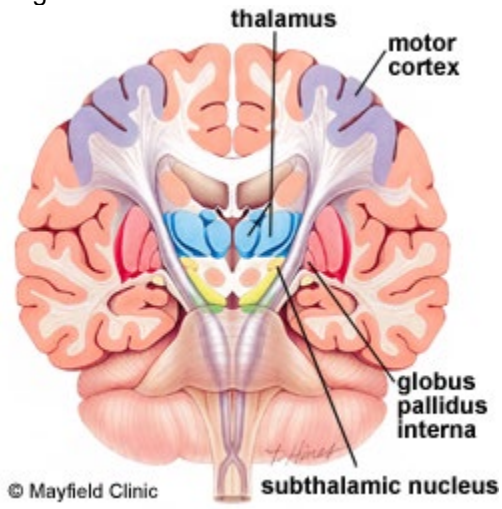



Image of Neurostimulation Sites in the Brain



# Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

*We* will:
Provide free aids and services to people with disabilities to communicate effectively with us, such as:
- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:
- Qualified interpreters
- Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *contract*, *your* id card, or aspirushealthplan.com.

If *you* believe that *we* have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, *you* can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

*You* can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help you.

*You* can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

# Language Assistance Services

**Albanian**: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1.866.631.5404 (TTY: 711).

**Arabic** تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً . اتصل بن اعلى رقم الهاتف 1.866.631.5404(رقم هاتف الصم والبك : 711)

**French**: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

**German**: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

**Hindi**: _यान द_: य_द आप ि◌हंदी बोलते ह_ तो आपके ि◌लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

**Hmong**: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

**Korean**: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

**Polish**: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

**Russian**: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1.866.631.5404 (телетайп: 711).

**Spanish**: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

**Tagalog**: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

**Traditional Chinese**: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請 致電 1.866.631.5404 (TTY:711).

**Vietnamese**: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

**Pennsylvania Dutch**: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

**Lao**: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັ້ງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.866.631.5404 (TTY:711).