PREMERA | BLUE CROSS

MEDICAL POLICY – 7.01.63
Deep Brain Stimulation

BCBSA Ref. Policy:	7.01.63
Effective Date:	July 1, 2018
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Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.20	Vagus Nerve Stimulation
7.01.125	Occipital Nerve Stimulation
7.01.143	Responsive Neurostimulation for the Treatment of Refractory Partial Epilepsy
7.01.546	Spinal Cord and Dorsal Root Ganglion Stimulation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Deep brain stimulation (DBS) can be used to treat essential tremor, Parkinson disease, and a movement disorder called dystonia. Deep brain stimulation is used when drugs aren't able to control symptoms. It works by blocking electrical signals in specific areas of the brain that control movement. Surgery is needed to place a thin metal rod, called an electrode, in the brain. (When severe movement affects both sides of the body, an electrode may be implanted on each side of the brain.) The electrode is attached to a small device called a neurostimulator, which is placed under the skin below the collar bone. Batteries power the neurostimulator to send electrical signals to the electrode. This policy describes when deep brain stimulation may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Application	Medical Necessity

DBS of the thalamus	**Deep brain stimulation of the thalamus may be considered medically necessary for:**
	• Unilateral treatment of disabling, medically unresponsive tremor* due to:
	  ○ Parkinson's disease
	  OR
	  ○ Essential Tremor
	• Bilateral treatment of disabling, medically unresponsive tremor* in both upper limbs due to:
	  ○ Parkinson's disease
	  OR
	  ○ Essential tremor
	
	*See **Definition of Terms**

DBS of the globus pallidus or subthalamic nucleus (unilateral or bilateral)	**Deep brain stimulation of the globus pallidus or subthalamic nucleus may be considered medically necessary for:**
	• Parkinson's disease with ALL of the following:
	  ○ A good response to levodopa
	  ○ Motor complications not controlled by drug treatment
	  AND
	  ○ One of the following:
	  ▪ A minimum score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale (UPDRS) when the patient has been without medication for approximately 12 hours
	  OR
	  ▪ Parkinson's disease for at least 4 years
	• Primary dystonia** with ALL of the following:
	  ○ Patients older than 7 years of age
	  AND
	  ○ Chronic, intractable (drug refractory)
	
	****Note:** may include generalized and/or segmental dystonia, hemidystonia, and

Application	Medical Necessity
	cervical dystonia (torticollis)

Application	Investigational

DBS for other disorders	**Deep brain stimulation is considered investigational for:**
	• Other disorders, including but not limited to:
	  ○ Multiple sclerosis
	  ○ Post-traumatic dyskinesia
	  ○ Tardive dyskinesia
	  ○ Chronic cluster headaches
	• Other psychiatric or neurologic diagnoses, including but not limited to:
	  ○ Alcohol addiction
	  ○ Alzheimer disease
	  ○ Anorexia nervosa
	  ○ Chronic pain
	  ○ Depression
	  ○ Epilepsy
	  ○ Obsessive-compulsive disorder
	  ○ Tourette syndrome

Documentation Requirements
The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include clinical documentation of: • Diagnosis/condition • History and physical examination documenting the severity of the condition • Area planned for deep brain stimulation (thalamus, globus pallidus, or subthalamic nucleus) • Response to levodopa • Unified Parkinson Disease Rating Scale score

Coding

Code	Description
CPT	
61850	Twist drill or burr hole(s) for implantation of neurostimulator or 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 (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	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)
61867	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
61868	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)
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
HCPCS	
L8680	Implantable neurostimulator electrode, each
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

Related Information

Definition of Terms

Disabling, medically unresponsive tremor is defined as **all** of the following:

- Tremor causing significant limitation in daily activities
- Inadequate control by maximal dosage of medication for at least 3 months before implant

Contraindications to deep brain stimulation include:

- Patients who are not good surgical risks because of unstable medical problems or because of the presence of a cardiac pacemaker
- Patients who have medical conditions that require repeated magnetic resonance imaging
- Patients who have dementia that may interfere with the ability to cooperate
- Patients who have had botulinum toxin injections within the last 6 months

Evidence Review

Background

Deep brain stimulation (DBS) is used as an alternative to permanent neuroablative procedures for control of essential tremor and Parkinson disease. DBS is also being evaluated for the treatment of a variety of other neurologic and psychiatric disorders.

Deep Brain Stimulation

Deep brain stimulation involves the stereotactic placement of an electrode into the brain (ie, hypothalamus, 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 patient returns 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, use of bilateral stimulation using 2 electrode arrays has also been investigated in patients with bilateral, severe symptoms. After implantation, noninvasive programming of the neurostimulator can be adjusted to the patient's symptoms. This feature may be important for patients with Parkinson disease (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 adverse effects of neurostimulation such as dysarthria, disequilibrium, or involuntary movements.

Essential Tremor and PD

DBS has been investigated as an alternative to permanent neuroablative procedures, such as thalamotomy and pallidotomy. DBS has been most thoroughly investigated as an alternative to thalamotomy for unilateral control of essential tremor (ET) and tremor associated with Parkinson's disease (PD). More recently, there has been research interest in the use of DBS of the globus pallidus or subthalamic nucleus as a treatment of other parkinsonian symptoms, such as rigidity, bradykinesia, or akinesia. Another common morbidity associated with PD is the occurrence of motor fluctuations, referred to as an "on and off" phenomena, related to the maximum effectiveness of drugs (ie, "on" state) and the nadir response during drug troughs (ie, "off" state). In addition, levodopa, the most commonly used anti-Parkinson drug, may be associated with disabling drug-induced dyskinesias. Therefore, the optimal pharmacologic treatment of PD may involve a balance between optimal effects on PD symptoms versus the appearance of drug-induced dyskinesias. The effect of DBS on both PD symptoms and drug-induced dyskinesias has also been studied.

Primary and Secondary Dystonia

DBS has also been investigated in patients with primary and secondary dystonia, defined as a neurologic movement disorder characterized by involuntary muscle contractions, which force certain parts of the body into abnormal, contorted, and painful movements or postures. Dystonia can be classified according to age of onset, bodily distribution of symptoms, and cause. Age of onset can occur during childhood or during adulthood. Dystonia can affect certain

portions of the body (focal dystonia and multifocal dystonia) or the entire body (generalized dystonia). Torticollis is an example of a focal dystonia. Primary dystonia is defined when dystonia is the only symptom unassociated with other pathology. Treatment options for dystonia include oral or injectable medications (ie, botulinum toxin) and destructive surgical or neurosurgical interventions (ie, thalamotomies or pallidotomies) when conservative therapies fail. Secondary dystonia is a dystonia brought on by an inciting event, such as a stroke, trauma, or drugs. Tardive dystonia is a form of drug-induced secondary dystonia.

Cluster Headaches

DBS has been investigated in patients with chronic cluster headaches. Cluster headaches occur as episodic attacks of severe pain lasting from 30 minutes to several hours. The pain is usually unilateral and localized to the eye, temple, forehead, and side of the face. Autonomic symptoms that occur with cluster headaches include ipsilateral facial sweating, flushing, tearing, and rhinorrhea. Cluster headaches occur primarily in men and have been classified as vascular headaches that have been associated with high blood pressure, smoking, and alcohol use. However, the exact pathogenesis of cluster headaches is uncertain. Positron emission tomography (PET) scanning and magnetic resonance imaging(MRI) have shown the hypothalamic region may be important in the pathogenesis of cluster headaches. Alterations in hormonal or serotonergic function may also play a role. Treatment of cluster headaches includes pharmacologic interventions for acute episodes and prophylaxis, sphenopalatine ganglion(SPG) blockade, and surgical procedures such as percutaneous sphenopalatine ganglion radiofrequency rhizotomy, and gamma knife radiosurgery of the trigeminal nerve.

Neurologic and Psychiatric Disorders

The role of DBS in treatment of other treatment-resistant neurologic and psychiatric disorders, particularly Tourette syndrome, epilepsy, major depressive disorders, and obsessive-compulsive disorder (OCD), is also being investigated. Ablative procedures are irreversible and, though they have been refined, remain controversial treatments for intractable illness. Interest has shifted to neuromodulation through DBS of nodes or targets within neural circuits involved in these disorders. Currently, a variety of target areas are being studied.

Summary of Evidence

For individuals who have essential tremor or tremor in PD who receive DBS of the thalamus, the evidence includes a systematic review and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review (a TEC Assessment) concluded that there was sufficient evidence that DBS of the thalamus results in clinically significant tremor suppression and that outcomes after DBS were at least as good as thalamotomy. Subsequent studies reporting long-term follow-up have supported the conclusions of the TEC Assessment and found that tremors were effectively controlled 5 to 6 years after DBS. The evidence is sufficient to determine thatthe technology results in a meaningful improvement in the net health outcome.

For individuals who have symptoms (eg, speech, motor fluctuations) associated with PD (advanced or >4 years in duration with early motor symptoms) who receive DBS of the globus pallidus interna (GPi) or subthalamic nucleus (STN), the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One of the systematic reviews (a TEC Assessment) concluded that studies on DBS of the GPi or STN have consistently demonstrated clinically significant improvements in outcomes (eg, neurologic function). Other systematic reviews also found significantly better outcomes after DBS than after a control intervention. An RCT in patients with levodopa-responsive PD of at least 4 years in duration and uncontrolled motor symptoms found that quality of life at 2 years was significantly higher when DBS was provided in addition to medical therapy. Meta-analyses of RCTs comparing DBS of the GPi and STN have reported mixed findings and have not shown that 1 type of stimulation is clearly superior to the other. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary dystonia who receive DBS of the GPi or STN, the evidence includes systematic reviews, an RCT, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A pooled analysis of 24 studies, mainly uncontrolled, found improvements in motor scores and disability scores after 6 months and at the last follow-up (mean, 32 months). A double-blind RCT found that severity scores improved more after active than after sham stimulation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have tardive dyskinesia or tardive dystonia who receive DBS, the evidence includes case series, one of which included a double-blind comparison of outcomes when the DBS device was turned on versus off. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Few studies were identified and they had small

sample sizes (range, 9-19 patients). Additional studies, especially RCTs or other controlled studies, are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have epilepsy who receive DBS, the evidence includes 2 systematic reviews of RCTs and many observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs were identified. The larger reported that DBS had a positive impact during some parts of the blinded trial phase but not others, and a substantial number of adverse events (in >30% of patients). The smaller RCT (N=16) showed a benefit with DBS. Many small observational studies reported fewer seizures compared with baseline, however, without control groups, interpretation of these results is limited. Additional trials are required to determine the impact of DBS on patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have multiple sclerosis (MS) who receive DBS, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT with 10 multiple sclerosis patients is insufficient evidence on which to draw conclusions about the impact of DBS in this population. Additional trials are required. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Tourette syndrome who receive DBS, the evidence includes crossover RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Several small (≤15 patients) crossover studies and a 2015 meta-analysis have suggested that DBS may improve outcomes in patients with Tourette syndrome. However, the optimal target of the brain for DBS is unknown, so additional controlled studies in larger numbers of patients are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have cluster headaches or facial pain who receive DBS, the evidence includes a randomized crossover study and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. In the randomized study, the between-group difference in response rates did not differ significantly between active and sham stimulation phases. Additional RCTs or controlled studies are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have treatment-resistant depression who receive DBS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The only double-blind, parallel-group RCT in patients with depression did not find that DBS significantly increased the response rate compared with sham; 2 other RCTs were stopped due to futility. A crossover controlled trial randomized patients to

active or to sham stimulation after a year of open-label stimulation. There was a greater reduction in symptom scores after active stimulation, but only in patients who were responders in the open-label phase; these findings may not be generalizable. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have obsessive-compulsive disorder who receive DBS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Among the RCTs on DBS for obsessive-compulsive disorder, only 1 has reported the outcome of greatest clinical interest (therapeutic response rate), and that trial did not find a statistically significant benefit for DBS compared to sham treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have anorexia nervosa, alcohol addiction, Alzheimer disease, Huntington disease, or chronic pain who receive DBS, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. RCTs are needed to evaluate the efficacy of DBS for these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01801319	A Clinical Evaluation of Subcallosal Cingulate Gyrus Deep Brain Stimulation for Treatment-Resistant Depression	40	Dec 2017 (ongoing)
NCT00640133	Effectiveness of Deep Brain Stimulation for Treating People with Treatment Resistant Obsessive-Compulsive Disorder	27	Feb 2018
NCT01983904	DBS for Treatment Resistant Depression (CRIO-DBS)	25	Mar 2018
NCT00367003	Deep Brain Stimulation for Treatment Resistant	20	Sep 2018

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Depression		
NCT02782533	DBS of the Third Ventricle for Cluster Headache and Obesity (DBS V3)	15	Nov 2018
NCT02601677	Deep Brain Stimulation of NAc/ALIC to Prevent Treatment-Refractory Obsessive Compulsive Disorder	10	Nov 2018
NCT02480803	Treatment in Advanced Parkinson's Disease: Continuous Intrajejunal Levodopa INfusion VErsus Deep Brain Stimulation	66	Dec 2018
NCT01329133	Deep Brain Stimulation and Obsessive-Compulsive Disorder (STOC2)	31	Jan 2019
NCT02773082[a]	Reclaim™ Deep Brain Stimulation (DBS) Therapy for Obsessive-Compulsive Disorder (OCD) (DBS)	50	Jan 2019
NCT02076698	Clinical and Medico-economical Assessment of Deep Brain Stimulation of the Anterior Nucleus of the Thalamus for the Treatment of Pharmacoresistant Partial Epilepsy	62	Dec 2019
NCT02056873	Tourette Syndrome Deep Brain Stimulation	20	Dec 2019
NCT01973478	Deep Brain Stimulation in Patients With Chronic Treatment Resistant Depression	40	Feb 2020
NCT01817517	Thalamic Deep Brain Stimulation for the Treatment of Refractory Tourette Syndrome	10	Apr 2020
NCT02535884[a]	Deep Brain Stimulation (DBS) of the Globus Pallidus (GP) in Huntington's Disease (HD) (HD-DBS)	50	Oct 2020
NCT01210781	Target Planning for Placement of DBS-electrodes and Follow-Up of the Clinical Efficacy of Stimulation	100	Dec 2020
NCT02937688[a]	Deep Brain Stimulation (DBS) for Parkinson's Disease International Study (REACH-PD)	264	Apr 2021
NCT01839396[a]	Implantable Neurostimulator for the Treatment of Parkinson's Disease (INTREPID)	310	Jul 2021
NCT00855621	Effects of Deep Brain Stimulation in Parkinson's Disease	70	Dec 2023
Unpublished			
NCT02583074	Subthalamic Deep Brain Stimulation in Patients With Medication-Refractory Primary Cranial-Cervical Dystonia: A Randomised, Sham-controlled Trial	40	Sep 2017 (unknown)

NCT: national clinical trial
a Denotes industry-sponsored or cosponsored trial

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 academic medical centers and 2 physician specialty societies while this policy was under review in 2014. Iinput supported the use of bilateral deep brain stimulation in patients with medically unresponsive tremor in both limbs.

Practice Guidelines and Position Statements

European Academy of Neurology

In 2016, the European Academy of Neurology(EAN) published guidelines on neuromodulation in management of chronic pain.[52] Due to "very low" quality of evidence, the Academy could not recommend deep brain stimulation (DBS) for treatment of neuropathic pain.

American Academy of Neurology

Essential Tremor

The American Academy of Neurology (AAN) published an updated guideline on the treatment of ET (essential tremor) in 2011.[53] This update did not change the conclusions and recommendations of the AAN 2005 practice parameters regarding DBS for ET.[54] The guidelines stated that bilateral DBS of the thalamic nucleus may be used to treat medically refractory limb tremor in both upper limbs (level C, possibly effective), but that there were insufficient data regarding the risk/benefit ratio of bilateral vs unilateral DBS in the treatment of limb tremor. There was insufficient evidence to make recommendations on the use of thalamic DBS for head or voice tremor (level U, treatment is unproven).

Parkinson Disease

The 2006 Guidelines from AAN on the treatment of Parkinson disease (PD) with motor fluctuations and dyskinesia found that, although the criteria are evolving, patients with PD considered candidates for DBS include levodopa-responsive, nondemented, and neuropsychiatrically intact patients who have intractable motor fluctuations, dyskinesia, or tremor.[55] AAN concluded that DBS of the subthalamic nucleus (STN) may be considered a treatment option in PD patients to improve motor function and to reduce motor fluctuations, dyskinesia, and medication usage (Level C – possibly effective), but found evidence insufficient to make any recommendations about the effectiveness of DBS of the globus pallidus or the ventral intermediate nucleus of the thalamus in reducing motor complications or medication usage, or in improving motor function in PD patients.

2010 Guidelines from AAN on the treatment of nonmotor symptoms of PD found insufficient evidence for the treatment of urinary incontinence with DBS of the STN.[56] AAN found that DBS of the STN possibly improves sleep quality in patients with advanced PD. However, none of the studies performed DBS to treat insomnia as a primary symptom, and DBS of the STN is not currently used to treat sleep disorders.

Tardive Syndromes

The 2013 guidelines[57] from AAN on the treatment of tardive syndromes were updated in 2018.[58] The latest guidelines state that "pallidal DBS possibly improves tardive dyskinesia and might be considered as a treatment for intractable tardive dyskinesia (Level C, which indicates that the treatment is possibly effective, based on ≥1 class II study and consistent with ≥2 class III studies).

European Society for the Study of Tourette Syndrome

The European Society for the Study of Tourette Syndrome published guidelines on DBS in 2011.[59] The guidelines state that DBS for Tourette syndrome is still in its infancy and that there are no randomized controlled trials that have included a sufficiently large number of patients. The Society suggested that DBS should only be used in adult, treatment-resistant, and severely affected patients, and highly recommended that DBS be performed in the context of controlled and double-blind trials including larger and carefully characterized groups of patients.

Canadian Network for Mood and Anxiety Treatments

The Canadian Network for Mood and Anxiety Treatments' 2009 clinical guidelines for management of major depressive disorder in adults found emerging evidence to support DBS as an experimental intervention for patients with treatment-refractory depression.[60] There was no consensus on the most effective target brain region for implantation, although 3 regions have been explored (subcallosal cingulated gyrus, the nucleus accumbens, and the ventral caudate/ventral striatum region).

American Society for Stereotactic and Functional Neurosurgery et al

The American Society for Stereotactic and Functional Neurosurgery and the Congress of Neurological Surgeons published a joint systematic review and guidelines on DBS for obsessive-compulsive disorder (OCD) in 2014.[48] The document concluded that there was a single level I study supporting the use of bilateral STN DBS for medically refractory OCD and a single level II study supporting bilateral nucleus accumbens DBS for medically refractory OCD. It also concluded that the evidence on unilateral DBS was insufficient.

National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Care Excellence (NICE) has published guidance documents on DBS, as discussed in the following subsections.

Tremor and Dystonia

In 2006, NICE made the same statement for use of DBS for treatment of both tremor and dystonia.[61] Unilateral and bilateral stimulation of structures responsible for modifying movements, such as the thalamus, globus pallidus, and the STN, which interact functionally with the substantia nigra, are included in both guidance statements. The guidance stated: "Current evidence on the safety and efficacy of deep brain stimulation for tremor and dystonia (excluding Parkinson's disease) appears adequate to support the use of this procedure."

Refractory Chronic Pain Syndromes (Excluding Headache)

The 2011 guidance from NICE indicated there is evidence that DBS is efficacious for refractory chronic pain (excluding headache) is associated with serious risks.[62] However, the procedure is "efficacious in some patients" refractory to other treatments. Patients should be informed that DBS may not control their chronic pain symptoms and that possible risks associated with this procedure include the small risk of death.

Intractable Trigeminal Autonomic Cephalgias

The 2011 guidance from NICE indicated that the evidence on the efficacy of DBS for intractable trigeminal autonomic cephalalgias (eg, cluster headaches) was "limited and inconsistent, and the evidence on safety shows that there were serious but well-known adverse effects."[63]

Refractory Epilepsy

The 2012 guidance from NICE indicated that the evidence on the efficacy of DBS for refractory epilepsy was limited in both quantity and quality: "The evidence on safety showed that there are serious but well-known adverse effects."[64]

Parkinson Disease

In 2003, NICE stated that the evidence on the safety and efficacy of DBS for treatment of Parkinson disease "appears adequate to support the use of the procedure."[65] The guidance noted that DBS should only be offered when Parkinson disease is refractory to best medical treatment.

Medicare National Coverage

Effective for services furnished on or after April 1, 2003, Medicare covers unilateral or bilateral thalamic ventralis intermedius nucleus DBS for the treatment of ET and/or parkinsonian tremor and unilateral or bilateral STN or globus pallidus interna DBS for the treatment of PD when the following conditions are met66:

- Devices must be approved by the Food and Drug Administration (FDA) for "DBS or devices used in accordance with FDA-approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials."
- For thalamic ventralis intermedius nucleus DBS, patients must meet ALL of the following criteria:
    - "Diagnosis of ET based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least 2 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.
    - "Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings."
- For STN or globus pallidus interna DBS, patients must meet ALL of the following criteria:
    - "Diagnosis of PD based on the presence of at least 2 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 (eg, dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy.
    - "Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings"

DBS is not covered for ET or PD patients 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 patient'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."

Regulatory Status

In 1997, the Activa® Tremor Control System (Medtronic) was cleared for marketing by the U.S. Food and Drug Administration (FDA) for DBS. The Activa® Tremor Control System consists of an implantable neurostimulator, a deep brain stimulator lead, an extension that connects the lead to the power source, a console programmer, a software cartridge to set electrical parameters for stimulation, and a patient control magnet, which allows the patient to turn the neurostimulator on and off, or change between high and low settings.

The original FDA-labeled indications for Activa® were limited to unilateral implantation of the device for the treatment of tremor, but, in 2002, FDA-labeled indications were expanded to include bilateral implantation as a treatment to decrease the symptoms of advanced PD not controlled by medication. In 2003, the labeled indications were further expanded to include "…unilateral or bilateral stimulation of the internal globus pallidus or subthalamic nucleus to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis) in patients seven years of age or above." This latter indication was cleared for marketing by FDA through the humanitarian device exemption (HDE) process. In 2017, the indications for PD were modified to include "adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson's Disease of at least 4 years' duration that are not adequately controlled with medication."

In 2009, the Reclaim® device (Medtronic), a DBS device, was cleared for marketing by FDA through the humanitarian device exemption process for the treatment of severe obsessive-compulsive disorder.

In 2014, the Brio Neurostimulation System (now called Infinity; St. Jude Medical Neuromodulation) was cleared for marketing by FDA for the treatment of Parkinsonian tremor.

In 2016, the St. Jude Medical's Infinity DBS device with directional leads was approved by FDA. The directional leads enable the clinician to "steer" current to different parts of the brain. This

tailored treatment reduces side effects. The Infinity system can be linked to Apple's iPod Touch and iPad Mini.

In December 2017, a second system with directional leads, the Vercise Deep Brain Stimulation System (Boston Scientific), was approved by FDA. This system is to be used as an adjunctive therapy from reducing motor symptoms of moderate-to-advanced levodopa-responsive PD inadequately controlled with medication alone.

PMA FDA product code: MHY

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History

Date	Comments
06/25/98	Add to Surgery Section - New Policy
01/07/99	Coding Update - 1999 CPT Coding Release.
05/09/00	Replace Policy - Policy reviewed; new information added on bilateral stimulation and different sites of stimulation; underlying policy statement unchanged.
06/02/00	Replace Policy - Added cross-references to other stimulation policies.
04/09/02	Replace Policy - Policy updated based on TEC Assessment; policy statement revised to

Date	Comments
	include a broader range of patients w/Parkinson's disease.
10/16/03	Replace Policy - Policy revised with focus on new FDA-labeled indication for primary refractory dystonia. Rest of policy statement is unchanged.
01/01/04	Replace Policy - CPT code updates only.
05/11/04	Replace Policy - Policy reviewed, additional CPT codes added. No change to policy statement.
06/14/05	Replace Policy - Policy revised with information and policy statement added on deep brain stimulation for cluster headaches. The previous policy statements are unchanged.
02/06/06	Codes updated - No other changes.
06/16/06	Replace Policy - Policy revised with literature review; references added; policy statements are unchanged. Scope and Disclaimer language updated.
01/26/07	Codes Updated - No other changes.
06/15/07	Cross Reference Update - No other changes.
11/13/07	Replace Policy - Policy revised with literature review; references added. Policy statement updated with treatment of other psychiatric or neurologic disorders is considered investigational.
12/11/07	Cross Reference Updated - No other changes.
04/08/08	Codes Updated - Added 61860, no other changes
12/16/08	Replace Policy - Policy statement clarified to state that score of 30 points must be within the Motor section of the UPDRS.
05/12/09	Replace Policy - Policy updated with literature search, no change to the policy statement. References added.
04/13/10	Cross Reference Update - No other changes.
06/13/11	Replace Policy - Policy updated with literature review; references 27-31 added. No change in policy statements.
04/17/12	Related Policies updated: 7.01.546 added to replace 7.01.25 which has been deleted.
08/20/12	Replace policy. Rationale section revised based on literature review through April 2012. References 23-24, 31, 37-38, 44-46 added, others renumbered or removed. Policy statements unchanged.
08/27/12	Update Related Policy – 7.01.20 is added. Update Coding Section – ICD-10 effective dates are now 10/01/2014.
10/17/12	Update Related Policies – Add 6.01.54.
10/14/13	Replace policy. Policy updated with literature review through May 20, 2013; reference 20 added; anorexia nervosa, alcohol addiction, and chronic pain added as investigational.

Date	Comments
12/08/14	Annual Review. Policy updated with literature review through June 11, 2014; clinical input reviewed; references 32, 41-43, and 52 added; bilateral stimulation of the thalamus may be medically necessary for bilateral tremor. ICD-9 and ICD-10 diagnosis and procedure codes removed; these are not utilized in adjudication of the policy.
01/26/15	Update Related Policies. Add 7.01.143.
12/08/15	Annual Review. Policy reviewed. No new references added. Policy statement unchanged.
07/01/16	Annual Review, approved June 14, 2016. Clarified that bilateral stimulation may be considered medically necessary for tremor in both upper limbs due to essential tremor or Parkinson disease. Policy updated with literature review through February 11, 2016. References 7, 10-11, 18, 22-26, 28, 33-34, and 36-38 added.
07/01/17	Annual Review, approved June 6, 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017. References 10, 13-16, 18, 36, and 42 added. In medically necessary statement on unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus, "OR Parkinson disease for at least 4 years" added to medically necessary criteria for use in Parkinson disease.
08/25/17	Coding update, removed CPT codes 95970, 95971, 95978, and 95979.
01/01/18	Coding update, removed CPT code 0169T as it was terminated 1/1/17.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; references 6-10, 17, 27-29, 31-32, 34, and 59 added. Policy statements reformatted for greater clarity.
03/01/19	Minor update, added Documentation Requirements section.

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Tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb. Tej zaum tsab ntawv tshaj xo no muaj cov ntsiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam los ntawm Premera Blue Cross. Tej zaum muaj cov hnub tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyoog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Iloko (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti apliksayonyo wenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente. Chiama 800-722-1471 (TTY: 800-842-5357).

日本語 (Japanese):
この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하는 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ລາວ (Lao):
ແຈ້ງການນີ້ມີຂໍ້ມູນສຳຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສຳຄັນກ່ຽວກັບຄຳຮ້ອງສະໝັກ ຫຼື ຄວາມຄຸ້ມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີສຳຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດຳເນີນການຕາມກຳນົດເວລາສະເພາະເພື່ອຮັກສາຄວາມຄຸ້ມຄອງປະກັນສຸຂະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເລື່ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄວ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໂທຫາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):
សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរ៉ាប់រងរបស់អ្នកតាមរយៈ Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ចេញសមត្ថភាព ដល់កំណត់ថ្ងៃជាក់ច្បាស់នានា ដើម្បីនឹងរក្សាទុកការជានាវ៉ាប់រងសុខភាពរបស់អ្នក ឬប្រាក់ជំនួយចេញផ្លែ។ អ្នកមានសិទ្ធិទទួលព័ត៌មាននេះ និងជំនួយនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

ਪੰਜਾਬੀ (Punjabi):
ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਜਿਸ ਜਵਚ ਖਾਸ ਤਾਰੀਖਾ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀ ਜਸਹਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ਼ ਤੋਂ ਪਹਿਲਾਂ ਕੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫ਼ਤ ਵਿੱਚ ਤੇ ਆਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):
این اعلامیه حاوی اطلاعات مهم میباشد .این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید .شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید .شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کاربران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):
To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócic uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):
Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastre de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența privitoare la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Fa'asamoa (Samoan):
Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'amatalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับการการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):
Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).