Subject: Deep Brain Stimulation for Intractable Pain

Policy Number: NMP39

Effective Date*: October 2003

Updated: August 2016

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This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document

For Medicaid Plans: Please refer to the appropriate State’s Medicaid manual(s), publication(s), citation(s), and documented guidance for coverage criteria and benefit guidelines prior to applying Health Net Medical Policies guidelines

The Centers for Medicare & Medicaid Services (CMS)
For Medicare Advantage members please refer to the following for coverage guidelines first:

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Instructions
- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under “Reference/Website” and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)
• If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
• If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

**Current Policy Statement**
Deep brain stimulation is considered medically necessary for treating patients with severe, chronic pain that is refractory to all other pain therapies when all of the following are met:

1. Persistent pain states for which no curative surgical therapy has a reasonable expectation of a better outcome than spinal stimulation.
2. Patient was carefully screened, evaluated and diagnosed by a multidisciplinary pain management team prior to application of these therapies
3. Pain relief from a temporarily implanted electrode has been demonstrated prior to permanent implantation
4. All facilities, equipment, professional and support personnel required for the proper diagnosis, treatment and follow-up of the patient are available

**Codes Related To This Policy**
NOTE:
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures have been replaced by ICD-10 code sets.

**ICD-9 Codes**
053.12 Postherpetic trigeminal neuralgia
053.13 Postherpetic polyneuralgia
337.22 Reflex sympathetic dystrophy of the lower limb
338.0 Central Pain Syndrome
338.21 - 338.29 Chronic pain
338.3 Neoplasm-related pain
338.4 Chronic pain syndrome
353.6 Phantom limb syndrome
355.71 Causalgia of the lower limb
355.8 Mononeuritis of lower limb, unspecified
722.10 Lumbar intervertebral disc without myelopathy
722.52 Lumbar or lumbosacral intervertebral disc
722.83 Postlaminectomy syndrome, lumbar region
723.4 Brachial neuritis or radiculitis NOS
723.5 Torticollis, unspecified
773.13 Pathologic fracture of vertebrae

**ICD-10 Codes** (Not an all inclusive list)

B02.22 Postherpetic trigeminal neuralgia
B02.23 Postherpetic polyneuropathy
G54.6 Phantom limb syndrome with pain
G57.70 Causalgia of unspecified lower limb
G57.71 Causalgia of right lower limb
G57.72 Causalgia of left lower limb
G57.90-G57.92 Unspecified mononeuropathy of lower limb
G89.0 -G89.4 Pain not elsewhere classified
G90.521- Complex regional pain syndrome I of lower limb
G90.529

M43.6 Torticollis
M48.50 Collapsed vertebra, not elsewhere classified
M51.26 Other intervertebral disc displacement, lumbar region
M51.27 Other intervertebral disc displacement, lumbosacral region
M51.36 Other intervertebral disc degeneration, lumbar region
M51.37 Other intervertebral disc degeneration, lumbosacral region
M54.12 Radiculopathy, cervical region
M54.13 Radiculopathy, cervicothoracic region
M80.08 Age-related osteoporosis with current pathological fracture, vertebra(e)
M84.48 Pathological fracture, other site
M84.68 Pathological fracture in other disease, other site
M96.1 Postlaminectomy syndrome, not elsewhere classified

**CPT Codes**

61863 Twist drill, burr hole, craniotomy or craniectomy for stereotactic implantation of one neurostimulator 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 for stereotactic implantation of one neurostimulator array in subcortical site (eg, thalamus, globus 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 (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

61880 Revision or removal of intracranial neurostimulator electrodes

61885 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling

61886 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays

61888 Revision or removal of cranial neurostimulator pulse generator or receiver

**HCPCS Codes**

L8680 Implantable neurostimulator electrode, each

L8681 Patient programmer (external) for use with implantable neurostimulator pulse generator

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

**Scientific Rationale – Update August 2015**

Jung et al (2015) reported that the major indication of subthalamic nucleus deep brain stimulation (STN DBS) is motor complications in advanced PD; however, pain reduction after STN DBS has been noted. They sought to evaluate the long-term effect of STN DBS on pain in PD. Twenty-four patients who underwent STN DBS at the Movement Disorder Center at Seoul National University Hospital from June 1, 2005, through March 31, 2006, were studied. The assessments of pain were performed preoperatively and 8 years after surgery. Because 13 of the total 24 patients had additional 2-year postoperative data, the serial change between the preoperative and the 2- and 8-year follow-ups after surgery was also evaluated. Motor symptoms were assessed using the Unified Parkinson's Disease Rating Scale and the Hoehn and Yahr staging scale. The severity of pain was scored according to an ordinal scale ranging from 0 (absent) to 10 (maximal pain) in 7 parts of the body (head, neck, trunk, and the upper and lower extremities on each side of the body). For each body part, the quality of pain was grouped into 1 of 4 categories: dystonic, musculoskeletal, radiculoneuritic, and central. Sixteen of the 24 patients (67%) experienced pain at baseline when not taking medication (off-state). All off-state pain at baseline improved or disappeared at 8 years after surgery. The number of
Body parts with pain was 21 at baseline and decreased to 11 at 8 years after the surgery. The mean (SD) and median scores of the off-state pain were 6.2 (2.5) and 7.0 at baseline and improved to 3.5 (2.2) and 2.5 at 8 years after the surgery, respectively. However, new pain developed in 18 of 24 patients (75%) during the 8-year follow-up period. The number of body parts with newly developed pain was 47, and the mean (SD) and median scores for new pain were 4.4 (3.0) and 3.0, respectively. The types of new pain at 8 years were musculoskeletal in 11 patients, central in 4 patients, radiculoneuritic in 3 patients, and dystonic in 1 patient. The authors conclude pain associated with PD is improved by STN DBS, and the beneficial effect persists after a long-term follow-up of 8 years. In addition, new pain, especially the musculoskeletal type, developed in most patients, becoming a long-term distressing problem.

Fontaine et al (2015) reported that medically refractory chronic cluster headache (CH) is a severely disabling headache condition for which several surgical procedures have been proposed as a prophylactic treatment. None of them have been evaluated in controlled conditions, only open studies and case series being available. Destructive procedures (radiofrequency lesioning, radiosurgery, section) and microvascular decompression of the trigeminal nerve or the sphenopalatine ganglion (SPG) have induced short-term improvement which did not maintain on long term in most of the patients. They carried a high risk of complications, including severe sensory loss and neuropathic pain, and consequently should not be proposed in first intention. Deep brain stimulation (DBS), targeting the presumed CH generator in the retro-hypothalamic region or fibers connecting it, decreased the attack frequency >50 in 60% of the 52 patients reported. Complications were infrequent: gaze disturbances, autonomic disturbances, and intracranial hemorrhage (2). Occipital nerve stimulation (ONS) was efficient (decrease of attack frequency >50%) in about 70% of the 60 patients reported, with a low risk of complications (essentially hardware related). Considering their respective risks, ONS should be proposed first and DBS only in case of ONS failure. New on-demand chronically implanted SPG stimulation seemed to be efficient to abort CH attacks in a pilot controlled trial, but its long-term safety needs to be further studied.

Cury et al (2014) prospectively evaluated the effect of subthalamic nucleus deep brain stimulation (STN-DBS) on the different characteristics of pain and other nonmotor symptoms (NMS) in patients with Parkinson disease (PD). Forty-four patients with PD and refractory motor symptoms were screened for STN-DBS. Patients were evaluated before and 1 year after surgery. The primary outcome was change in pain prevalence after surgery. Secondary outcome measures were changes in motor function (Unified Parkinson's Disease Rating Scale), characteristics of pain and other NMS using specific scales and questionnaires, and quality of life. Forty-one patients completed the study. The prevalence of pain changed from 70% to 21% after surgery (p < 0.001). There were also significant improvements in pain intensity, NMS, and quality of life after STN-DBS (p < 0.05). Dystonic and musculoskeletal pain responded well to DBS, while central pain and neuropathic pain were not influenced by surgery. There was a strong correlation between the change in pain intensity and the improvement in quality of life (r = 0.708, p < 0.005). No correlation was found between pain improvement and preoperative response to levodopa or motor improvement during stimulation (r = 0.247, p = 0.197 and r = 0.249, p = 0.193, respectively) or with changes in other NMS. The authors concluded STN-DBS decreased pain after surgery, but had different effects in different types of PD-related pain. Motor and nonmotor symptom improvements after STN-DBS did not correlate with pain relief.
**Scientific Rationale – Update August 2013**

Boccard et al (2013) prospectively assessed long-term efficacy of deep brain stimulation (DBS) for chronic neuropathic pain in a single-center case series. Patient reported outcome measures were collated before and after surgery, using a visual analog score, short-form 36-question quality-of-life survey, McGill pain questionnaire, and EuroQol-5D questionnaires (EQ-5D and health state). One hundred ninety-seven patients were referred over 12 years, of whom 85 received DBS for various etiologies: 9 amputees, 7 brachial plexus injuries, 31 after stroke, 13 with spinal pathology, 15 with head and face pain, and 10 miscellaneous. Mean age at surgery was 52 years, and mean follow-up was 19.6 months. Contralateral DBS targeted the periventricular gray area (n = 33), the ventral posterior nuclei of the thalamus (n = 15), or both targets (n = 37). Almost 70% (69.4%) of patients retained implants 6 months after surgery. Thirty-nine of 59 (66%) of those implanted gained benefit and efficacy varied by etiology, improving outcomes in 89% after amputation and 70% after stroke. In this cohort, >30% improvements sustained in visual analog score, McGill pain questionnaire, short-form 36-question quality-of-life survey, and EuroQol-5D questionnaire were observed in 15 patients with >42 months of follow-up, with several outcome measures improving from those assessed at 1 year. Investigators concluded DBS for pain has long-term efficacy for select etiologies. Clinical trials retaining patients in long-term follow-up are desirable to confirm findings from prospectively assessed case series.

**Scientific Rationale – Update September 2011**

According to a 2011 guidance from the National Institute for Health and Clinical Excellence (NICE), “Current evidence on the safety of deep brain stimulation (DBS) for refractory chronic pain syndromes (excluding headache) shows that there are serious but well-known risks. There is evidence that the procedure is efficacious in some patients who are refractory to other forms of pain control.” They note further that DBS should only be used in patients with refractory chronic pain syndromes that other treatments have failed to control.

**Scientific Rationale – Update January 2011**

Intracranial neurostimulation for pain relief is most frequently delivered by stimulating the motor cortex, the sensory thalamus, or the periaqueductal and periventricular gray matter. The stimulation of these sites through MCS (motor cortex stimulation) and DBS (deep brain stimulation) has been shown to be effective for treating a number of neuropathic and nociceptive pain states that are not responsive or amenable to other therapies or types of neurostimulation, however, prospective randomized trials confirming the efficacy of these therapies are lacking. DBS has been investigated for the treatment of cluster headaches, chronic low back pain, failed back surgery syndrome, and peripheral neuropathic pain and other nociceptive and neuropathic pain states.

Fontaine et al (2010) performed a prospective crossover, double-blind, multicenter study assessing the efficacy and safety of unilateral hypothalamic DBS in 11 patients with severe refractory CCH. The randomized phase compared active and sham stimulation during 1-month periods, and was followed by a 1-year open phase. The severity of CCH was assessed by the weekly attacks frequency (primary outcome), pain intensity, sumatriptan injections, emotional impact (HAD) and quality of life (SF12). Tolerance was assessed by active surveillance of behavior, homeostatic and hormonal functions. During the randomized phase, no significant change in primary
and secondary outcome measures was observed between active and sham stimulation. At the end of the open phase, 6/11 responded to the chronic stimulation (weekly frequency of attacks decrease [50%]), including three pain-free patients. There were three serious adverse events, including subcutaneous infection, transient loss of consciousness and micturition syncopes. No significant change in hormonal functions or electrolytic balance was observed. The investigators concluded randomized phase findings of this study did not support the efficacy of DBS in refractory CCH, but open phase findings suggested long-term efficacy in more than 50% patients, without high morbidity. They recommended the discrepancy between these findings justifies additional controlled studies.

Prévinaire et al (2009) evaluated the efficacy of brain stimulation (deep brain stimulation (DBS) and motor cortex stimulation (MCS) within the framework of neuropathic pain management in spinal cord injury (SCI) patients. The methodology used, proposed by the French Society of Physical Medicine and Rehabilitation (SOFMER), includes a systematic review of the literature, the gathering of information regarding current clinical practices and a validation by a multidisciplinary panel of experts. The authors reported that DBS is more effective on nociceptive pain than deafferentation pain. For the central pain of SCI patients, the long-term efficacy of DBS is quite low (three patients out of 19, amounting to 16%). MCS seems to have an interesting potential with a long-term efficacy of 57% (four patients out of seven), with less complications than DBS. The authors concluded for central pain in SCI patients, there is no sufficient level of evidence to validate the use of DBS. There is however a low level of evidence for MCS. They concluded these results must be validated by larger comparative or controlled versus placebo clinical studies.

Scientific Rationale - Update September 2005
A Medline search of the published peer review literature revealed no new information to support any revisions to this current policy. In recent reports, the use of deep brain stimulation has been suggested in the treatment of intractable chronic cluster headache, epilepsy, and obsessive-compulsive disorders. Published data is limited and study population numbers have been low. There is inadequate evidence in the peer-reviewed published medical literature regarding its long-term efficacy, therefore, for these indications the use of deep brain stimulation remains experimental and investigational.

Note: The use of Deep Brain Stimulation for Movement Disorders is addressed in a separate medical policy.

Scientific Rationale - Initial
Deep brain stimulation is based on the theory that neurons control the "touch" sensation, as well as other neurons that send pain signals to the brain. Pain involves nerve endings in various parts of the body. These nerve endings connect up through the spinal cord to the brain. Spinal cord and deep brain stimulation may be used for patients with pain that cannot be managed by treating the problem that causes the pain, or by exercises, medications or other therapies. The theory is that to stimulate the "touch" neurons (dorsal columns) may dull the pain signals from the "pain" neurons. To stimulate the "touch" neurons, some wires have to be placed directly on these cells, which are either deep in the brain or inside the spinal cord. Electrodes are implanted by stereotactic methods in specific regions of the brain (e.g., the thalamus and peri-aqueductal gray matter). Once the electrodes and wires are placed by surgery, electricity is used to stimulate the nerves.
Deep brain stimulation (DBS) certainly is not considered an early-line treatment for chronic pain, but it can be very useful in certain patients. The technique involves placing the patient in a stereotactic head frame under local anesthesia and mild sedation. Magnetic resonance or computed tomography images are then obtained to stereotactically localize the target sites, typically the periventricular and periaqueductal gray matter of the mesencephalic-diencephalic transition area, the specific sensory thalamic nuclei, the internal capsule, and the motor cortex. Once the coordinates for the target site are obtained, an electrode is placed into the brain via a burr hole under local anesthesia and sedation. Electrophysiologic recording of motor and sensory responses with a stimulating electrode guide the neurosurgeon to the ultimate placement of the permanent DBS electrode. After the electrode is placed in the appropriate position, the patient is given general anesthesia and the proximal lead is tunneled in the subcutaneous space to the infraclavicular space of the chest, where it is attached to a pulse generator, much as a cardiac pacemaker is implanted. The pulse generator can be programmed to various settings by external interrogation.

A long-term follow-up study found DBS to be most effective for failed back syndrome, trigeminal neuropathy and peripheral neuropathy, whereas patients with thalamic pain, spinal cord injury, and postherpetic neuralgia did poorly. The majority of the patients in this study had failed back syndrome, and of these 91% had early pain relief and 74% continued to have long-term relief. A distinct advantage of DBS over ablative procedures is that it is potentially nondestructive and reversible.

**Review History**

October 16, 2003 Medical Advisory Council, initial review  
September, 2005 Update – September, 2005 – no revisions  
March 2006 Code update/revisions  
August 2012 Update - no revisions. Codes updated.  
August 2015 Update – no reviews. Code updates  
August 2016 Update - no reviews. Code updates

**This policy is based on the following evidence-based guidelines:**


**References - Update August 2016**

References – Update August 2015

References – Update August 2014

References – Update August 2013

References – Update August 2012
References – Update January 2011

References – Update September 2005

References - Initial

Important Notice

General Purpose.
Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

No Medical Advice.
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member’s Contract Controls Coverage Determinations.
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member’s contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member’s contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member's contract shall govern. The Policies do not replace or amend the Member's contract.

Policy Limitation: Legal and Regulatory Mandates and Requirements
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

**Reconstructive Surgery**
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. "Reconstructive surgery" means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

1. To improve function or
2. To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean "cosmetic surgery," which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

**Reconstructive Surgery after Mastectomy**
California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

**Policy Limitations: Medicare and Medicaid**
Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.