Occipital Nerve Stimulation
Corporate Medical Policy

File name: Occipital Nerve Stimulation
File code: UM.SPSVC.14
Origination: 2011
Last Review: 11/2015
Next Review: 12/2016
Effective Date: 5/01/2016

Description/Summary

Occipital nerve stimulation (ONS) delivers a small electrical charge to the occipital nerve in an attempt to prevent migraines and other headaches in patients who have not responded to medications. The device consists of a subcutaneously implanted pulse generator (in the chest wall or abdomen) attached to extension leads that are tunneled to join electrodes placed across 1 or both occipital nerves at the base of the skull. Continuous or intermittent stimulation may be used.

The literature to date on the use of ONS consists primarily of small case series, small randomized trials and 2 small crossover studies. While the case series report substantial benefit, treatment-related improvements in the randomized controlled trials (RCTs) were modest. RCTs (to account for potential placebo effect) with greater numbers of patients and longer follow-up are needed. It is noted that a number of trials are in progress. At this time, the available evidence is insufficient to permit conclusions concerning the impact of ONS on net health outcome. In addition, no implanted occipital nerve stimulators have received U.S. Food and Drug Administration (FDA) approval. Therefore, ONS is considered investigational.

Policy

Occipital nerve stimulation is considered investigational for all indications.

Policy Guidelines

Coding Information

Click the links below for attachments, coding tables & instructions.
Attachment I - CPT & HCPCS Code Table & Instructions

Background

Implanted peripheral nerve stimulators have been used for treatment of refractory pain for many years, but have only recently been proposed for management of craniofacial pain. Occipital, supraorbital, and infraorbital stimulation have been reported in the literature.
There are 4 types of headache: vascular, muscle contraction (tension), traction, and inflammatory. Primary (not the result of another condition) chronic headache is defined as headache occurring more than 15 days of the month for at least 3 months. An estimated 45 million Americans experience chronic headaches. For at least half of these people, the problem is severe and sometimes disabling.

Migraine is the most common type of vascular headache. Migraine headaches are usually characterized by severe pain on 1 or both sides of the head, an upset stomach, and, at times, disturbed vision. One-year prevalence of migraine ranges from 6% to 15% in adult men and from 14% to 35% in adult women. Migraine headaches may last a day or more and can strike as often as several times a week or as rarely as once every few years. Drug therapy for migraine is often combined with biofeedback and relaxation training. Sumatriptan is commonly used for relief of symptoms. Drugs used to prevent migraine include methysergide maleate, propranolol hydrochloride, ergotamine tartrate; amitriptyline, valproic acid, and verapamil.

Hemicrania continua, also a vascular headache, causes moderate pain with occasional severe pain on only one side of the head. At least one of the following symptoms must also occur; conjunctival injection and/or lacrimation, nasal congestion and/or rhinorrhea, or ptosis and/or miosis. Headache occurs daily and is continuous with no pain-free periods. Hemicrania continua occurs mainly in women, and its true prevalence is not known. Indomethacin usually provides rapid relief of symptoms. Other nonsteroidal anti-inflammatory drugs, including ibuprofen, celecoxib, and naproxen, can provide some relief from symptoms. Amitriptyline and other tricyclic antidepressants are effective in some patients.

Cluster headache is a vascular headache that occurs in cyclical patterns or clusters of severe or very severe unilateral orbitoal or supraorbital and/or temporal pain. The headache is accompanied by at least one of the following autonomic symptoms: ptosis (drooping eyelid), conjunctival injection, lacrimation, rhinorrhea, and, less commonly, facial blushing, swelling, or sweating. Bouts of 1 headache every other day to 8 attacks per day may last from weeks to months, usually followed by remission periods when the headache attacks stop completely. The pattern varies from 1 person to another, but most people have 1 or 2 cluster periods a year. During remission, no headaches occur for months, and sometimes even years. The intense pain is caused by the dilation of blood vessels, which creates pressure on the trigeminal nerve. While this process is the immediate cause of the pain, the etiology is not fully understood. It is more common in men than in women. One-year prevalence is estimated to be 0.5 to 1.0 in 1000. Management of cluster headache consists of abortive and preventive treatment. Abortive treatments include subcutaneous injection of sumatriptan, topical anesthetics sprayed into the nasal cavity, and strong coffee. Some patients respond to rapidly inhaled pure oxygen. A variety of other pharmacologic and behavioral methods of aborting and preventing attacks have been reported with wide variation in patient response.

Rationale/Scientific Background

This policy has been updated periodically using the MEDLINE database. The most recent literature review was performed through October 7, 2014.
Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. It is recognized that RCTs are particularly important to assess treatments of painful conditions, due to the expected placebo effect and the subjective nature of pain assessment in general. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition.

Controlled Trials

Migraine

Three randomized trials with over 100 patients and a smaller randomized crossover study have been identified.

The Occipital Nerve Stimulation for the Treatment of Intractable Chronic Migraine Headache (ONSTIM) trial, was a multicenter, randomized feasibility study of occipital nerve stimulation (ONS) for treatment of intractable chronic migraine headache that was published in 2011. The trial was designed to evaluate the study design and did not have a single primary end point. One hundred ten patients were enrolled, and patients who had a positive response to a short-acting occipital nerve block were randomized as follows: 33 to adjustable stimulation (AS), 17 to preset stimulation (PS) of 1 min/d, and 17 to medical management (MM). At the 3-month evaluation, the responder rate (percentage of patients who achieve 50% or more reduction in number of headache days per month or a 3-point or greater reduction in average overall pain intensity compared with baseline) was 39% in the AS group, 6% in the PS group, and 0% in the MM group. Lead migration occurred in 12 of 51 (24%) of subjects and 3 subjects required hospitalization for adverse events (infection, lead migration, nausea). Limitations of the study include a short observation period and the inability to effectively blind subjects and investigators to treatment group.

This report was followed in 2012 by an industry-sponsored U.S. Food and Drug Administration (FDA) regulated double-blind trial that randomized 157 patients in a 2:1 ratio to active or sham stimulation. Intention-to-treat (ITT) analysis revealed no significant difference between the groups in the percentage of patients who achieved 50% or greater reduction in visual analog scale scores for pain at 12 weeks (active, 17.1%; control, 13.5%). More patients in the ONS group improved in the number of headache days, migraine-related disability, and direct reports of pain, although the benefits were modest. The most common adverse event was persistent implant site pain. Results from the 52-week open-label extension of this study were published in 2014. Results were reported for the ITT population and for the 125 patients who met criteria for intractable chronic migraine. Twenty-four patients were excluded from analysis due to explantation of the system (n=18) or other loss to follow-up. Mean headache days at baseline were 21.6 for the ITT population and 24.2 for the intractable chronic migraine group. In the ITT population, headache days were
reduced by 6.7 days, and a 50% or greater reduction in headache days and/or pain intensity was observed in 47.8% of patients. Sixty-eight percent of patients were satisfied with the headache relief provided by the device. Seventy percent experienced at least 1 of 183 device-related adverse events, of which 8.6% required hospitalization and 40.7% required surgical intervention. Eighteen percent of patients had persistent pain and/or numbness with the device.

A third multicenter double-blind, randomized, sham-controlled trial with 140 patients was reported in abstract form in 2009; results were negative and a full report has not been published. Serra and Marchioretto conducted a randomized crossover study in which 30 patients with chronic migraine (100% of patients) and medication overuse headache (85% of patients) were implanted with an occipital nerve stimulator and randomized to “stimulation on” or “stimulation off” arms. After 1 month, or if headaches worsened during the off period, patients were crossed over to the other arm. At baseline, the average frequency of migraines was 5.8 days per week and the median headache severity was 8 on an 11-point numeric rating scale. The number of headaches decreased from a median of 6.3 days per week in the off phase to 2.1 days per week in the on phase (p<0.05). The median Migraine Disability Assessment score decreased from 79 at baseline to 10 at 12-month follow-up (p<0.001). Quality of life measured by the 36-Item Short-Form Health Survey (SF-36) was significantly improved, use of triptans decreased from a median of 20 to 3 doses/month, and use of nonsteroidal anti-inflammatory drugs decreased from a median of 25.5 to 2 doses/month. There were 2 infections (6.7%) and 3 lead migrations (10%) during the study. This study is limited by the lack of a control group during follow-up and lack of blinding.

Hemicrania Continua
Six patients with hemicrania continua received continuous unilateral ONS in a crossover study by Burns et al. in 2008. Pain on a 10-point scale was recorded hourly in patient diaries, and the Migraine Disability Assessment was administered at each follow-up visit. Four of 6 patients reported substantial improvement (80%-95%), 1 reported a 30% improvement, and 1 reported that pain was worse by 20%. Adverse events were mild and associated with transient overstimulation.

Cluster Headache
Burns et al reported on 14 patients with cluster headache in 2009. At a median follow-up of 17.5 months (range, 4-35 months), 10 of 14 patients reported improvement. Three reported improvement of 90% or better, 3 reported moderate improvement (30%-60%), and 4 reported mild improvement (20%-30%). Four patients required new electrode leads. A wide range of stimulation was used. Six patients required battery replacement. In 2011, Mueller et al reported a prospective study of 10 patients with refractory chronic cluster headache who had been treated with bilateral ONS. At a mean follow-up of 12 months (range, 3-18 months), the frequency of the attacks were reduced by a mean of 44% (range, 20%-90%) in 90% of the patients. The daily frequency of the attacks dropped from a mean of 6 to 3. Seventy percent of the patients required less medication during attacks. There was a nonsignificant tendency for improvement on the SF-36 in this small study.

Another publication from 2011 reported mean 37-month follow-up (range, 11-64 months) on 15 patients with intractable chronic cluster headache. The mean duration
of cluster headache was 7 years, with a mean 2.5 attacks per day. One patient had an immediate postoperative infection and was explanted. For the remaining 14 patients, the mean attack frequency decreased from 2.24 to 0.12 per day. Twelve patients reported total or partial relief and 2 had no or minimal improvement. Two patients found the ONS-related paresthesias to be unbearable. In some patients contralateral attacks occurred. Technical problems included battery depletion (64%) and infection (20%). Five patients (33%) had the stimulators removed due to discomfort or infection, and 9 patients (60%) were reported to be pain-free for extended periods.

**Headache Associated With Chiari Malformation**
Vadivelu et al reported on a series of 22 patients with Chiari malformation and persistent occipital headaches. Of the 22, 15 (68%) had a successful occipital neurostimulator trial and underwent permanent implantation. At a mean follow-up of 18.9 months (range, 6-51 months), 13 of the 15 patients (87%) reported pain relief of greater than 50%. Device-related complications requiring additional surgeries (lead migration, uncomfortable position of generator, wound infection) occurred in 40% of patients during the follow-up period.

**Combined Occipital and Supraorbital Stimulation**
Combined occipital and supraorbital neurostimulation was evaluated in 7 patients with chronic migraine by Reed et al. Responses to 2 stimulation programs were evaluated: one that stimulated only the occipital leads and one that stimulated both the occipital and supraorbital leads together. With follow-up ranging from 1 to 35 months, all patients reported a full therapeutic response but only to combine supraorbital-occipital neurostimulation.

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in September 2013 identified a number of clinical trials that are currently underway. Of particular note are the following:

- NCT01151631 is a randomized double-blind multicenter trial sponsored by Leiden University Medical Center that will compare low (30%) and high (100%) stimulation parameters in patients with medically intractable chronic cluster headache. Enrollment of 144 patients is anticipated with a targeted completion date in January 2014. The status of this study is unknown.
- Boston Scientific began a randomized trial (OPTIMIZE) in 2013 to evaluate the Precision™ system for ONS for migraine (NCT01775735). The study lists an estimated enrollment of 180 patients with completion expected June 2016.
- NCT01842763 is a French database of patients suffering from refractory chronic headache disorders (chronic migraine, cluster headache, chronic paroxysmal hemicranias, SUNCT syndrome, hemicrania continua, cervicogenic headache disorders), and treated by ONS. The study has an estimated enrollment of 50 and an expected completion date of December 2016.
- ONS is also being studied for the treatment of fibromyalgia (NCT01298609). This study had an enrollment of 40 and is listed as completed. As of October 2014, no results have been posted.

**Summary of Evidence**
The literature to date on the use of occipital nerve stimulation (ONS) consists primarily of small case series, small randomized trials and 2 small crossover studies.
While the case series report substantial benefit, treatment-related improvements in the randomized controlled trials (RCTs) were modest. RCTs (to account for potential placebo effect) with greater numbers of patients and longer follow-up are needed. It is noted that a number of trials are in progress. At this time, the available evidence is insufficient to permit conclusions concerning the impact of ONS on net health outcome. In addition, no implanted occipital nerve stimulators have received U.S. Food and Drug Administration approval. Therefore, ONS is considered investigational.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

The 2013 Guidance from the United Kingdom’s National Institute for Health and Care Excellence (NICE) states that the evidence on ONS for intractable chronic migraine shows some efficacy in the short term but there is very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. NICE recommends that clinicians wishing to undertake ONS for intractable chronic migraine should ensure that patients understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information.

Regulatory status

As of September 2014, FDA has not cleared any ONS device for treatment of headache. The Synergy™ IPG (implantable pulse generator) device from Medtronic received marketing clearance in 1999 for management of chronic, intractable pain of the trunk or limbs, and off-label use for headache is described in the literature. The Genesis™ neuromodulation system (St. Jude Medical) is approved by FDA for spinal cord stimulation and the Eon™ stimulator has received CE mark approval in Europe for the treatment of chronic migraines. Medtronic and Boston Scientific Neuromodulation Systems (Precision™) are currently conducting clinical trials of devices.

Reference Resources

Blue Cross and Blue Shield Association. Occipital Nerve Stimulation. MPRM# 7.01.125. Last review November 2014.


Policy Implementation/Update information

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<thead>
<tr>
<th>Year</th>
<th>Details</th>
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<td>2011</td>
<td>New policy</td>
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<tr>
<td>11/2015</td>
<td>Adoption of BCBSA MPRM# 7.01.125. Code table updates.</td>
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Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract language, the member’s contract language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.
Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required for services as outlined in this policy. Benefits are subject to all terms, limitations and conditions of the subscriber contract.

An approved referral authorization for members of the New England Health Plan (NEHP) is required. A prior approval for Access Blue New England (ABNE) members is required. NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member’s health plan.

Federal Employee Program (FEP) members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure.

Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through a self-funded (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s plan documents or contact the customer service department.

Approved by BCBSVT Medical Directors Date Approved

Joshua Plavin, MD
Senior Medical Director
Chair, Medical Policy Committee

Robert Wheeler MD
Chief Medical Officer

Attachment I
CPT & HCPCS Code Table & Instructions

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Description</th>
<th>Policy Instructions</th>
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<td>The following codes will be denied as Not Medically Necessary, Contract Exclusions or Investigational.</td>
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<td>Code</td>
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<td>61885</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array</td>
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<td>61886</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays</td>
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<td></td>
<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrode array; cranial nerve</td>
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<td></td>
<td>64568</td>
<td>Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
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<td>Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator</td>
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<td>Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
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<td>HCPCS</td>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<td>HCPCS</td>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
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<td>L8682</td>
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The following code is unlisted and requires clinical documentation at time of claims submission. Clinical documentation will be reviewed and coverage determination will be made by a medical director.

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