Occipital Nerve Stimulation
Corporate Medical Policy

File name: Occipital Nerve Stimulation
File code: UM.SPSVC.14
Origination: 2011
Last Review: 11/2017
Next Review: 11/2018
Effective Date: 05/01/2018

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.

Coding Information
Click the links below for attachments, coding tables & instructions.
Attachment 1- CPT® & HCPCS Code Table & Instructions

Policy Guidelines
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
Headache

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 consecutive months. An estimated 45 million Americans experience chronic headaches. For at least half of these people, the problem is severe and sometimes disabling. Herein, we will only discuss types of vascular headache, including migraine, hemicrania continua, and cluster.

Migraine

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 and other triptans are commonly used for relief of symptoms. Drugs used to prevent migraine include amitriptyline, propranolol and other β-blockers, topiramate and other antiepileptic drugs, and verapamil.

Hemicrania Continua

Hemicrania continua causes moderate and occasionally severe pain on only 1 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 of symptoms. Amitriptyline and other tricyclic antidepressants are effective in some patients.

Cluster Headache

Cluster headache occurs in cyclical patterns or clusters of severe or very severe unilateral orbital or supraorbital and/or temporal pain. The headache is accompanied by at least one of the following autonomic symptoms: ptosis, conjunctival injection, lacrimation, rhinorrhea, and, less commonly, facial blushing, swelling, or sweating. Bouts of 1 headache every other day up 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 person to person, 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 woman. One-year prevalence is estimated to be 0.5 to 1.0 in 1000. Management of cluster headache consists of abortive and preventative 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

For individuals who have migraine headaches refractory to preventive medical management who receive occipital nerve stimulation, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Systematic reviews identified 5 sham-controlled randomized trials. Findings from pooled analyses of these RCTs were mixed. For example, compared to placebo, response rates to occipital nerve stimulation did not differ significantly but did reduce the number of days with prolonged moderate-to-severe headache. Occipital nerve stimulation was also associated with a substantial number of minor and serious adverse events. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have non-migraine headaches (eg, hemicrania continua, cluster headaches) who receive occipital nerve stimulation, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Many of the case series had small sample sizes; series with over 25 patients were available only for treatment of cluster headache. Although the case series tended to find that a substantial number of patients improved after occipital nerve stimulation, these studies lacked blinding and comparison groups. RCTs are needed to compare outcomes between occipital nerve stimulation and comparators (eg, to control for a potential placebo effect). The evidence is insufficient to determine the effects of the technology on health outcomes.

Regulatory status

The U.S. Food and Drug Administration (FDA) has not cleared or approved any occipital nerve stimulation device for treatment of headache. In 1999, the Synergy™ IPG device (Medtronic), an implantable pulse generator, was approved by FDA through the premarket approval process 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) was approved by FDA for spinal cord stimulation and the Eon™ stimulator has received CE mark approval in Europe for the treatment of chronic migraines.

Reference Resources

Blue Cross and Blue Shield Association. Occipital Nerve Stimulation. MPRM# 7.01.125. Last review April 2017.


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.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

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. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.

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 an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

<table>
<thead>
<tr>
<th>Year</th>
<th>New policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>New policy</td>
</tr>
<tr>
<td>11/2015</td>
<td>Adoption of BCBSA MPRM# 7.01.125. Code table updates.</td>
</tr>
<tr>
<td>11/2017</td>
<td>Updated policy/references from BCBSA MPRM# 7.01.125. Policy statements remain unchanged. Added descriptor to code L8689 added to PA list.</td>
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Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors

Gabrielle Bercy-Roberson, MD, MPH, MBA
Senior Medical Director
Chair, Health Policy Committee

Joshua Plavin, MD, MPH, MBA
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>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<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>
<td>Prior Approval Required</td>
</tr>
<tr>
<td>CPT®</td>
<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>
<td>Prior Approval Required</td>
</tr>
<tr>
<td>CPT®</td>
<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrode array; cranial nerve</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td>CPT®</td>
<td>64568</td>
<td>Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
<td>Prior Approval Required</td>
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<tr>
<td>CPT®</td>
<td>64569</td>
<td>Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator</td>
<td>Prior Approval Required</td>
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</tr>
<tr>
<td>CPT®</td>
<td>64570</td>
<td>Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
<td>Prior Approval Required</td>
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<tr>
<td>HCPCS</td>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
<td>Prior Approval Required. This code is Investigational for occipital nerve stimulation.</td>
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<tr>
<td>HCPCS</td>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
<td>Prior Approval Required. This code is Investigational for occipital nerve stimulation.</td>
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<tr>
<td>HCPCS</td>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
<td>Prior Approval Required. This code is Investigational for occipital nerve stimulation.</td>
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<tr>
<td>HCPCS</td>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
<td>Prior Approval Required. This code is Investigational for occipital nerve stimulation.</td>
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<tr>
<td>HCPCS</td>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
<td>Prior Approval Required. This code is Investigational for occipital nerve stimulation.</td>
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<tr>
<td>HCPCS</td>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, nonchargeable, includes extension</td>
<td>Prior Approval Required. This code is Investigational for occipital nerve stimulation.</td>
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<tr>
<td>HCPCS</td>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
<td>Prior Approval Required. This code is Investigational for occipital nerve stimulation.</td>
</tr>
<tr>
<td>HCPCS</td>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, norechargeable, includes extension</td>
<td>Prior Approval Required. This code is Investigational for occipital nerve stimulation.</td>
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<tr>
<td>HCPCS</td>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator, replacement only</td>
<td>Prior Approval Required. This code is Investigational for occipital nerve stimulation.</td>
</tr>
</tbody>
</table>

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.

| CPT  | 64999 | Unlisted procedure, nervous system | Clinical documentation is required at time of claims submission for medical review. |