**Occipital Nerve Stimulation**

**Introduction**

The occipital nerves run through the muscles on the back of the head and over the scalp. Irritation to these nerves can create shooting or tingling pain, usually on one side of the head or near one eye. The scalp can also be very painful to the touch. Occipital nerve stimulation is a technique being studied as a technique for migraines and other headaches that don’t respond to medication. Occipital nerve stimulation aims to treat pain with electrical signals. Wires are implanted at the base of the skull. The wires are connected to a small power source surgically placed below the skin, usually in the upper chest. The power source generates the electricity, which then sends the signal through the wires to stimulate the occipital nerve. It’s thought that the electrical signals block or scramble the pain signals from the nerves. Because more studies are needed to see if this technique is effective, occipital nerve stimulation is considered investigational (unproven).

**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

#### Service

<table>
<thead>
<tr>
<th>Occipital nerve stimulation</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occipital nerve stimulation is considered investigational for all indications.</td>
<td></td>
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</table>

#### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrodes; cranial nerve</td>
</tr>
<tr>
<td>64568</td>
<td>Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
</tr>
<tr>
<td>64569</td>
<td>Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>64570</td>
<td>Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
</tr>
<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8684</td>
<td>Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes</td>
</tr>
</tbody>
</table>
### Code | Description
---|---
| | extension
| L8686 | Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
| L8687 | Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
| L8688 | Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
| L8689 | External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
| L8689 | External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

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### Related Information

N/A

### Evidence Review

### Description

Occipital nerve stimulation 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 one or both occipital nerves at the base of the skull. Continuous or intermittent stimulation may be used.
Background

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 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 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 one 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.

Treatment

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 amitriptyline, propranolol and other β-blockers, topiramate and other antiepileptic drugs, and verapamil.

Hemicrania Continua

Hemicrania continua causes moderate pain with occasionally 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 occur mainly in women, and its true prevalence is not known.
Treatment

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

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 (drooping eyelid), 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 by 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 common in men than in woman. One-year prevalence is estimated to be 0.5 to 1.0 in 1000.

Treatment

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.

Peripheral Nerve Stimulators

Implanted peripheral nerve stimulators have been used to treat refractory pain for many years, but have only recently been proposed to manage craniofacial pain. Occipital, supraorbital, and infraorbital stimulation have been reported in the literature.
Summary of Evidence

For individuals with migraine headaches refractory to preventive medical management who receive occipital nerve stimulation, the evidence includes randomized controlled trials (RCTs), a systematic review of RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Systematic review identified 5 sham-controlled RCTs. 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.

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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>Ongoing</td>
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<tr>
<td>NCT01775735</td>
<td>Occipital Nerve Stimulation (ONS) for Migraine: OPTIMISE</td>
<td>180</td>
<td>Jun 2017 (ongoing)</td>
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<td>Unpublished</td>
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<tr>
<td>NCT01842763</td>
<td>French Database of Occipital Nerves Stimulation in</td>
<td>50</td>
<td>Dec 2016</td>
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<tr>
<td>NCT No.</td>
<td>Trial Name</td>
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<td>Completion Date</td>
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</tr>
<tr>
<td></td>
<td>the Treatment of Refractory Chronic Headache Disorders (NGO)</td>
<td></td>
<td>(unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

a Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

**Congress of Neurological Surgeons**

The 2015 evidence-based guidelines from the Congress of Neurological Surgeons stated “the use of occipital nerve stimulation is a treatment option for patients with medically refractory occipital neuralgia.” The statement had a level III recommendation based on a systematic review of literature that only identified case series.

**National Institute for Health and Care Excellence**

Guidance from the National Institute for Health and Care Excellence (2013) noted that the evidence on occipital nerve stimulation for intractable chronic migraine showed “some efficacy in the short term but very little evidence about long term outcomes. With regard to safety, there is a risk of complications, needing further surgery.”

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Regulatory Status**

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

**References**


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/13/10</td>
<td>Add to Surgery Section - New Policy</td>
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<tr>
<td>05/10/11</td>
<td>Replace Policy - Policy updated with literature search, reference 6 updated, reference 7 added; policy statement unchanged. CPT coding updated in Policy Guidelines. ICD-10 codes added to policy.</td>
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<td>01/06/12</td>
<td>Replace Policy – Policy updated with literature search through August 2011; references 7 and 8 added and references reordered; policy statement unchanged.</td>
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<tr>
<td>04/17/12</td>
<td>Related Policies updated: 7.01.546 added to replace 7.01.25 which has been deleted.</td>
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<tr>
<td>09/26/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<td>10/17/12</td>
<td>Update Related Policies – Add 7.01.135.</td>
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<tr>
<td>10/16/13</td>
<td>Update Related Policies. Change title to policy 7.01.135.</td>
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<td>Replace policy. Policy updated with literature review through September 27, 2013. References 2, 13 added; others renumbered/removed. Policy statement unchanged. ICD-10-PCS codes removed; this is an outpatient procedure and they would not apply.</td>
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<td>05/23/14</td>
<td>Update Related Policy. Add 7.01.555.</td>
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<tr>
<td>10/22/14</td>
<td>Update Related Policies. Remove 7.01.135 as it was archived.</td>
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<tr>
<td>01/28/15</td>
<td>Annual Review. Policy updated with literature review through October 7, 2014; reference 3 added; some references removed; policy statement unchanged.</td>
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<tr>
<td>01/29/16</td>
<td>Minor update. Added HCPCS code L8679.</td>
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