MEDICAL POLICY – 7.01.125
Occipital Nerve Stimulation

SELECT A HYPERLINK BELOW TO BE DIRECTED TO THAT SECTION.

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

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Introduction

Occipital nerve stimulation is a being studied as a new treatment for migraines and other headaches that don't respond to medication. 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 aims to treat pain with electrical signals. Wires are implanted at the base of the skull. They 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 stimulates the occipital nerve through the wires in the base of the neck. It’s believed that the electrical signals block or scramble the pain signals from the nerves. Because more studies are needed to see if this treatment 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

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Occipital nerve stimulation</strong></td>
<td>Occipital nerve stimulation is considered investigational for all indications.</td>
</tr>
</tbody>
</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>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 (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
</tr>
<tr>
<td>64569</td>
<td>Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>64570</td>
<td>Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
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</tbody>
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<table>
<thead>
<tr>
<th><strong>HCPCS</strong></th>
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<tbody>
<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 extension</td>
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</tbody>
</table>
### Code and Description

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension</td>
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<tr>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator, replacement only</td>
</tr>
<tr>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator, replacement only</td>
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</tbody>
</table>

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### Related Information

N/A

### Evidence Review

### Description

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 which is attached to extension leads. These leads are tunneled beneath the skin to join electrodes placed across one or both occipital nerves at the base of the skull. Continuous or intermittent stimulation may be used.
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.

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.

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. The 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

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 occur 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

Cluster headache is a vascular headache that occurs in cyclical patterns or clusters. The headaches are severe or very severe and occur on only one side of the head. The pain is either orbital, supraorbital, and/or temporal. 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. Clusters of one 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 one 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.

Cluster headaches are 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 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.

Summary of Evidence

The evidence for occipital nerve stimulation in individuals who have migraine headaches refractory to preventive medical management 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; one was judged to be at low risk of bias. Findings from pooled analyses of 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. Moreover, occipital nerve stimulation was 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.

The evidence for occipital nerve stimulation in individuals who have non-migraine headache (eg, hemicrania continua, cluster) 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, and 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. Moreover, RCTs are needed to compare outcomes between occipital nerve stimulation and controls to assess for the 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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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
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<td></td>
<td></td>
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<tr>
<td>NCT01842763</td>
<td>French Database of Occipital Nerves Stimulation in the Treatment of Refractory Chronic Headache Disorders (NGO)</td>
<td>50</td>
<td>Dec 2016 (ongoing)</td>
</tr>
<tr>
<td>NCT01775735*</td>
<td>Occipital Nerve Stimulation (ONS) for Migraine OPTIMISE</td>
<td>180</td>
<td>Jun 2017</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

Congress of Neurological Surgeons

A 2015 evidence-based guideline from the Congress of Neurological Surgeons states: “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

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 offer 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.

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

To date 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 (implantable pulse generator), was approved by the 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) 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.

References


<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>
</tr>
<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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<tr>
<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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</table>
### Date | Comments
--- | ---
10/17/12 | Update Related Policies – Add 7.01.135.
01/29/13 | Replace policy. Policy updated with literature search through August 2012; references 2 and 10 added and references reordered; policy statement unchanged.
10/16/13 | Update Related Policies. Change title to policy 7.01.135.
01/21/14 | 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.
05/23/14 | Update Related Policy. Add 7.01.555.
10/22/14 | Update Related Policies. Remove 7.01.135 as it was archived.
01/28/15 | Annual Review. Policy updated with literature review through October 7, 2014; reference 3 added; some references removed; policy statement unchanged.
01/29/16 | Minor update. Added HCPCS code L8679.

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  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  • Qualified interpreters
  • Information written in other languages

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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
Office for Civil Rights Complaint Portal, available at
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Email AppealsDepartmentInquiries@Premera.com

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Avi sila a gen Efòmasyon Enpòtàn ladan. Avi sila a kapab genyen enfòmasyon enpòtàn konpòsan aplikasyon w l’o wa konpòsan kouvèti asirans lan atravé Premera Blue Cross. Kapab genyen dat ki enpòtàn nan av si a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka menbe kouvètì asirans sante w la o wa pou yo ka ede w avèk depans yo. Se do w pou resew na enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

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Hmoob (Hmong):

Illokoo (Ilocano):
Daytoy a Pakdaak ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaak mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyon wno coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelsa iti daytoy a pakdaak. Mabalin nga adda rumbeng nga aramidenyo nga addang saksay dagiti partikular a naituding nga adda lawt tapno mapagtalinangetdyo ti coverag ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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Katagalog (Tagalog):

Polski (Polish):

Português (Portuguese):
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