



**BlueCross BlueShield
of Vermont**

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Corporate Medical Policy

Occipital Nerve Stimulation

File name: Occipital Nerve Stimulation

Origination: 1/2011

Last Review: N/A

Next Review: 01/2012

Effective Date: 07/01/2011

Description

Occipital nerve stimulation has been proposed for the treatment of patients with intractable head and neck pain that cannot be managed by more conservative treatments. It involves the use of a neurostimulator to deliver low-voltage electrical impulses via insulated lead wires that run under the skin and up to the occipital nerve. Implanted peripheral nerve stimulators have been used for treatment of refractory pain for many years but only recently proposed for management of craniofacial pain. Occipital, supraorbital, and infraorbital stimulation have been reported in the literature.

Policy

BCBSVT/TVHP (the Plan) considers occipital nerve stimulation for the treatment of intractable head and neck pain as **investigational** and unproven. The Plan also considers occipital nerve stimulation and supraorbital nerve stimulation **investigational** for the treatment of cluster headache and other chronic headaches because their effectiveness for these indications has not been established.

BlueCard/National Account Issues

State or federal mandates (e.g., FEP) may dictate that all devices, drugs, or biologics approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these devices may be assessed only on the basis of their medical necessity.

Policy Implementation/Update information

New Policy 01/2011

Scientific Background and Reference Resources

1. Technology Assessment: Occipital nerve stimulation is a procedure where electrodes are placed over the occipital nerve either unilaterally or bilaterally. An extension lead is tunneled under the skin to a site in the torso where an impulse generator or radiofrequency receiver is secured in a subcutaneous pocket. Patients use a remote control to electrically stimulate the nerve, which results in paraesthesia. In most reported cases, patients are fitted with an external trial stimulator before they undergo permanent implantation.
2. Literature Review: Published peer-reviewed literature shows ONS is being evaluated as a treatment for refractory head and neck pain. Most studies have small patient

populations and limited reported follow up times. The longest follow up being an average of 25 months after implantation. A common adverse effect was lead migration and a few patients experienced infections after implantation. Overall, many patients with a permanently implanted device experienced some pain relief. While many of the small studies showed positive outcomes in pain relief, there is currently no long term follow up data reporting on ongoing safety and efficacy.

3. Paemeleire and Bartsch (2010) identified encouraging results in published studies, but consider the technology to be emerging and more data is needed from ongoing controlled trials.
4. Another 2010 report by Goadsby and Sprenger found neuromodulation approaches, such as ONS, for acute migraine to offer much promise.
5. Trentman et al. (2010) reported on the results of 5 patients implanted with ONS for refractory headache disorders. While their results were positive, the authors concluded further studies are needed to correlate occipital nerve stimulator placement under general anesthesia and long-term headache control.
6. Burns et al (2008) studied fourteen patients with medically intractable chronic cluster headaches (CCH). Participants were implanted with bilateral electrodes in the suboccipital region for occipital nerve stimulation (ONS). Twelve patients used the stimulation continuously while two used it intermittently. A retrospective assessment of their clinical outcome was obtained. At a median follow-up of 17.5 months (range 4–35 months), 10 of 14 patients reported improvement and 9 of these recommend ONS. Three patients noticed a marked improvement of 90% or better (90%, 90%, and 95%), 3 a moderate improvement of 40% or better (40%, 50%, and 60%), and 4 a mild improvement of 20–30% (20%, 20%, 25%, and 30%). Improvement occurred within days to weeks for those who responded most and patients consistently reported their attacks returned within hours to days when the device was off. One patient found that ONS helped abort acute attacks. Adverse events of concern were lead migrations and battery depletion. The authors concluded that ONS offers a safe, effective option for some patients with CCH, however, more research is required to evaluate safety and efficacy of this therapy.
7. Paemeleire et al. (2010) recruited patients with medically refractory head pain treated with ONS to participate in a retrospective study including clinical review and possible indomethacin test to establish the headache phenotype according to the International Classification of Headache Disorders, 2nd Ed (ICHD-II). Data was gathered from questionnaires before implantation, at 1 month follow-up, and at long-term follow up. The duration of long-term follow-up was not identified. 26 patients were evaluated and phenotyped. A significant decrease in all pain parameters and analgesic use was noted at one month and the long-term follow up. Paemeleire et al. reported patient satisfaction to be as high as 80% of patients had greater than or equal to 50% pain relief at long-term follow-up. Overall complications rates were low, but there were frequent revisions. Phenotyping revealed two main groups: 8 patients had Migraine without aura (ICHD-II 1.1), and 8 had constant pain caused by compression, irritation or distortion of cranial nerves or upper cervical roots by structural lesions (ICHD-II 3.12). Authors noted overuse of symptomatic acute headache treatments was associated with less favorable long-term outcome in migraine patients. The data led Paemelerie et al. to conclude careful phenotyping of patients may help define subgroups more likely to respond to ONS. They suggest a controlled prospective study for ONS in ICHD-II 3.12.
8. Schwedt, et al. (2007) evaluated 15 patients implanted with an occipital nerve stimulator to treat intractable headache. The patients suffered from chronic migraine, chronic cluster

- headaches, and hemicrania continua, and post-traumatic headaches. Eight patients had bilateral lead placement and seven patients underwent unilateral lead placement. Patients were evaluated after 5-24 months. In all patients, the six mean headache measures improved significantly and headache frequency per 90 days improved. About 60% of the patients required revision to the implanted leads within one year and one patient needed generator revision. Overall, Schwedt, et al. found occipital nerve stimulation to be effective in some patients with intractable headache, but more safety and efficacy data are needed from prospective, randomized, sham-controlled studies.
9. Jasper and Hayek (2008) conducted a literature review to evaluate current evidence of occipital nerve stimulation as an effective treatment for benign headache. Using AHRQ criteria, they assessed the evidence and found: No randomized controlled trials (RCT) were identified. All of the articles reported positive outcomes including improved pain relief, reduced frequency, intensity, and duration of headaches with reduced medication consumption. ONS was reportedly successful for 70 - 100% of patients. Reduction of pain in patients with occipital headaches and transformed migraine is significant and rapid; for cluster patients the improvement may be less dramatic and it may take several months of occipital stimulation to achieve relief. No long-term adverse events occurred. Several short-term incidents occurred including infection, lead displacement, and battery depletion. The body of evidence as a whole is a level of strength of IV, limited. Based on the evidence, Jasper and Hayek concluded ONS is a useful tool in the treatment of chronic severe headaches with at least Level IV (limited) evidence based on multiple positive studies.
 10. Slavin, Nersesyan and Wess (2006) evaluated 10 patients implanted with peripheral nerve stimulators to treat occipital neuralgia. Seven of the ten patients continued to experience beneficial effects of stimulation during follow up (follow mean 22 months). Two patients had the systems removed due to loss of stimulation effect or significant pain improvement. One patient had the implant removed due to infection. The researchers concluded the beneficial effect from chronic stimulation persisted in more than half of the patients. Oh et al. (2004) studied 20 patients, 10 with occipital neuralgia and 10 with transformed migraine. Patients were followed up for an average of six months. 85 percent of patients reported excellent pain relief from the stimulation. 15 percent of patients reported good pain relief. Some adverse effects reported in the study included infection (2 patients) and electrode migration (7 patients).
 11. Melvin et al. (2007) produced a preliminary report showcasing 14 patients treated with a 4-10 day trial stimulation to treat intractable C2-medicated occipital headache. 11 of the 14 patients had the system permanently implanted following the trial and were followed up for 3 months. After the 12 weeks all patients thought the procedure was worthwhile. Of the 11, one patient had lead migration and one temporarily lost stimulation due to a loose lead connection.

At this time, there is not enough robust evidence in peer-reviewed literature to support the use of ONS for the treatment of pain.

Peer Reviewed Publications:

1. Burns B, Watkins L, Goadsby P. Treatment of intractable chronic cluster headache by occipital nerve stimulation in 14 patients. *Neurology*. 2009; 72(4):341-345.
2. Burns B, Watkins L, Goadsby PJ (2007) Treatment of medically intractable cluster headache by occipital nerve stimulation: long-term follow-up of eight patients. *Lancet*. 2007; 369:1099-1106.
3. Johnstone CSH Occipital nerve stimulation for the treatment of occipital neuralgia – eight case studies. *Neuromodulation*. 2006; 9:41-47.

4. Magis D, Allena M, Bolla M et al. Occipital nerve stimulation for drug-resistant chronic cluster headache: a prospective pilot study. *Lancet Neurology*. 2007; 6:314-321.
5. Schwedt T. Occipital nerve stimulation for medically intractable headache. *Current Pain and Headache Reports*. 2008; 12:62-66.
6. Schwedt TJ, Dodick DW, Hentz J et al. Occipital nerve stimulation for chronic headache – long-term safety and efficacy. *Cephalalgia*. 2007; 26:1025-1027.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Boston Scientific. A Prospective, Randomized, Double-Blind, Placebo-Controlled Trial of Occipital Nerve Stimulation for Drug Refractory Migraine. NLM Identifier: NCT00747812. Last updated on April 10, 2009. Available at: <http://www.clinicaltrials.gov/ct2/show/NCT00747812?term=occipital+nerve+stimulation+migraine&rank=3> Accessed on February 3, 2010.
2. Medtronic Neuro. ONSTIM: Occipital Nerve Stimulation for the Treatment of Intractable Migraine. NLM Identifier: NCT00200109. Last updated on April 9, 2009. Available at: <http://www.clinicaltrials.gov/ct2/show/NCT00200109?term=occipital+nerve+stimulation+migraine&rank=1>
3. Trentman TL, Rosenfeld DM, Vargas BB et al. Greater occipital nerve stimulation via the Bion Microstimulator; implantation technique and stimulation parameters *Clinical Trial*: NCT00205894. *Pain Physician* 2009; 12(3):621-8.
4. Schwedt TJ, Dodick DW, Trentman TL et al. Occipital nerve stimulation for chronic headache--long-term safety and efficacy. *Cephalalgia* 2007; 27(2):153-7.
5. Schwedt TJ, Dodick DW, Trentman TL et al. Response to occipital nerve block is not useful in predicting efficacy of occipital nerve stimulation. *Cephalalgia* 2007; 27(3):271-4.
6. Burns B, Watkins L, Goadsby P. Treatment of intractable chronic cluster headache by occipital nerve stimulation in 14 patients. *Neurology* 2009; 72(4):341-5.
7. Burns B, Watkins L, Goadsby P. Treatment of hemicrania continua by occipital nerve stimulation with a bion device: long-term follow-up of a crossover study. *Lancet Neurol* 2008; 7(11):1001-12.
8. Reed KL, Black SB, Bant CJ 2nd et al. Combined occipital and supraorbital neurostimulation for the treatment of chronic migraine headaches: initial experience. *Cephalalgia* 2009 Sep 3 [Epub ahead of print].
9. Clinical Trials.gov. Accessible at <http://clinicaltrials.gov/ct2/results?term=occipital+nerve+stimulation>

Approved by BCBSVT and TVHP Medical Directors

Date Approved

Antonietta Sculimbene MD (BCBSVT)

Chair, Medical Policy Committee

Attachment I

The following CPT and HCPCS codes are considered investigational for all ICD-9 and ICD-10 diagnosis codes:

HCPCS	L8680	Implantable neurostimulator electrode, each
	L8681- L8689	Implantable neurostimulator programmer and pulse generator code range

CPT:

61885- Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array

61886 with connection to 2 or more electrode arrays

64553; 64555 – Percutaneous implantation of neurostimulator electrodes; cranial nerve

64568 – Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

64569 – Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator or electrode array, including connection to existing pulse generator

64570 – Removal of cranial nerve stimulator (eg, vagus nerve) neurostimulator electrode array and pulse generator

64574; 64575 – Incision for implantation of neurostimulator electrodes; cranial nerve

64585 – Revision or removal of peripheral neurostimulator electrodes

64590 – Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

64595 – Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

64999- Unlisted procedure, nervous system

95970 – Electronic analysis in implanted Neurostimulator pulse generator system (eg, rate, pulse amplitude and duration configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) Neurostimulator pulse generator/transmitter, without reprogramming

95974 – Complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour

95975 – Complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour