Subject: Occipital Nerve Stimulation for Intractable Head and Neck Pain

Overview: 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.

Policy and Coverage Criteria:

HPHC does NOT cover occipital nerve stimulation for the treatment of intractable head and neck pain. It is considered experimental/investigational and unproven.

Exclusions: N/A

Supporting Information:

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.

Kinfe et al. (2014) reviewed studies to evaluate the usefulness and predictive value of occipital nerve block prior to occipital nerve stimulation for the treatment of head and neck pain. The review identified 133 individuals with chronic migraine and 7 with chronic cluster headache who received preoperative nerve block. The literature analysis did not show the preoperative nerve block sufficiently predicted the responsiveness to nerve stimulation. Kinfe et al. noted this issue requires further investigation.

Dodick et al. (2014) discussed results of a double-blinded RCT evaluating the peripheral nerve stim of occidptal nerves for the management of chronic migraine. Subjects were implanted with a neurostimulation system, randomized to an active or control group for 12 weeks, and received open-label treatment for an additional 40 weeks. Outcomes collected included number of headache days, pain intensity, migraine disability assessment (MIDAS), Zung Pain and Distress (PAD), direct patient reports of headache pain relief, quality of life, satisfaction and adverse events. Statistical tests assessed change from baseline to 52 weeks using paired t-tests. Intent-to-treat (ITT) analyses of all patients (N = 157) and analyses of only patients who met criteria for intractable chronic migraine (ICM; N = 125) were performed. Results found headache days were significantly reduced in the ITT and ICM populations. The percentages of patients who achieved a 30% and 50% reduction in headache days and/or...
pain intensity were 59.5% and 47.8%, respectively. However, even with half the patients in each cohort reporting satisfaction with headache relief, a total of 183 device/procedure-related adverse events occurred during the study, of which 18 (8.6%) required hospitalization and 85 (40.7%) required surgical intervention; 70% of patients experienced an adverse event. The authors noted results supported 12-month efficacy, but more emphasis is needed on adverse event mitigation in future research.

Young (2014) reviewed studies evaluating ONS for chronic migraine. Young highlighted that results of controlled trials have been mixed, with 2 RCTs showing meaningful efficacy and another RCT having no positive effect. Brewer et al. (2012) conducted a retrospective review of patients implanted with ONS. Based on phone interview or chart review, ONS was deemed successful in 5 of 12 migraine patients, 4 of 5 cluster headache, and 5 of 8 miscellaneous headache patients were also deemed a success. ONS therapy was documented for as long as 102 months. Among the patients with success, headache frequency was decreased by 18%, severity by 27% and migraine disability score by 50%. 58% of patients required at least one lead revision. The authors noted their results suggest ONS can be effective in the long-term. However, the small number of patients and retrospective nature of the study do not allow for definitive conclusions. RCTs are needed to better establish long-term efficacy.

A 2012 review by Magis et al. discussed current evidence on neurostimulation techniques for treatment of primary headache disorders. Their review of studies evaluating ONS found better evidence to support chronic cluster headache. However, more long-term studies including sham arms are necessary to better establish the efficacy of the technique.

Serra and Marchioretto reported results of a prospective, randomized cross-over study. Patients with chronic migraine or medication overuse headaches were implanted with ONS and randomized to stimulation on and stimulation off arms. Patients crossed over after one month or when headaches worsened. 29 patients completed the study. Headache intensity and frequency were significantly lower in the on arm than in the off arm. QOL significantly improved over the study. 5 adverse events occurred: 2 infections and 3 lead migraines. Length of follow up was one year. Serra and Marchioretto found ONS to be safe and effective treatment for carefully selected CM and MOH patients.

Magis et al. (2011) reported long-term results (range of 11-64 months) of 15 patients implanted with ONS for treatment of drug-resistant chronic cluster headache. The mean follow up was about 36 months. 11 of 14 patients reported at least a 90% improvement with 60% reporting being pain-free for prolonged periods. Follow up was collected via questionnaire after the surgery. 2 patients did not respond or had only mild improvement. Issues included significant lead migration in one patient, battery depletion, and ONS paresthesias. The authors found ONS to be effective, safe and well-tolerated. However, they noted the occurrence of contralateral attacks and isolated autonomic attacks in nearly half of the responders may have therapeutic and pathophysiological implications.

Mueller et al. (2011) reported on results of 10 patients treated with ONS for CCH. Baseline results of headache frequency, intensity, and duration were assessed with a 30-day diary. Standardized questionnaires were used to collect data pre- and post-operatively. Mean follow up was 12 months. All patients responded to ONS. Frequency, duration and severity of cluster attacked were reduced in 90% of patients. 70% of patients needed less medication during attacks. All patients reported QOL improvements. 2 patients required additional surgery. The researchers found ONS to be a valuable tool for treating patients with refractory CCH. However, optimal parameters for stimulation regarding pulse width and frequency remain unclear.

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. Another 2010 report by Goadsby and Sprenger found neuromodulation approaches, such as ONS, for acute migraine to offer much promise. 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.

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.

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.

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.

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.

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).

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.

3. Benchmarks:
BCBS MA: Not covered for any indication

Anthem BCBS NH: Occipital nerve stimulation is considered investigational and not medically necessary for all indications.
http://www.anthem.com/medicalpolicies/policies/mp_pw_c108472.htm

United Health Care: Neurostimulation or electrical stimulation of the occipital nerve is unproven for the treatment of occipital neuralgia or cervicogenic headache.

Aetna: Transcutaneous electrical nerve stimulation is also considered experimental and investigational for acute and chronic headaches, deep abdominal pain, pelvic pain, temporomandibular joint (TMJ) pain and all other indications because there is inadequate scientific evidence to support its efficacy for these specific types of pain.
http://www.aetna.com/cpb/medical/data/1_99/0011.html

Aetna considers the following interventions experimental and investigational for the treatment of occipital neuralgia because their effectiveness for this indication has not been established:
- Auriculotemporal nerve block
- Cervical rhizotomy
- Cryo-denervation
- Dorsal column stimulation
- Electrical stimulation of the occipital nerve
- Ganglionectomy
- Neurectomy
- Neurolysis of the great occipital nerve with or without section of the inferior oblique muscle
- Occipital nerve block
- Supraorbital nerve block
- Suprascapular nerve block
- Surgical release of the lesser occipital nerve within the trapezius and other procedures to decompress occipital nerves.

Aetna considers occipital nerve stimulation and supraorbital nerve stimulation experimental and investigational for the treatment of cluster headache and other chronic headaches because their effectiveness for these indications has not been established.
http://www.aetna.com/cpb/medical/data/700_799/0707.html

CIGNA: CIGNA does not cover ANY of the following local injection therapies or neurosurgeries for the treatment of cervicogenic headache or occipital neuralgia because these interventions are considered experimental, investigational or unproven (this list may not be all-inclusive):
- botulinum toxin type A*
- cervical microdecompression surgery (Jho Procedure)
- discectomy and spinal fusion
- electrical stimulation of occipital nerve
- ganglionectomy
- nerve root decompression
- neurectomy
- occipital nerve neurolysis
- radiofrequency denervation of cervical facet joints
- radiofrequency ablation of the planum nuchale
- rhizotomy
http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0063_coveragepositioncriteria_local_injection_therapy.pdf
4. Governmental/Professional Agencies:

CMS: Not covered
http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=240&ncdver=1&CoverageSelection=National&KeyWord=electrical+stimulator&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAA&

Codes:
ICD-9 Codes
339.00 – Cluster headache syndrome, unspecified
339.01 – Episodic cluster headache
339.02 – Chronic cluster headache
339.03 – Episodic paroxysmal hemicranias
339.04 – Chronic paroxysmal hemicranias
339.05 – Short lasting unilateral neuralgiform headache with conjunctival injection and tearing
339.09 – Other trigeminal autonomic cephalgias
339.10 – Tension type headache, unspecified
339.11 – Tension type headache, unspecified
339.12 – Chronic tension type headache
339.20 – Post-traumatic headache unspecified
339.21 – Acute post-traumatic headache
339.22 – Chronic post-traumatic headache
339.3 – Drug induced headache, not elsewhere classified
339.41 – Hemicrania continua
339.42 – New daily persistent headache
339.43 – Primary thunderclap headache
339.44 – Other complicated headache syndrome
339.81 – Hypnic headache
339.82 – Headache associated with sexual activity
339.83 – Primary cough headache
339.84 – Primary exertional headache
339.85 – Primary stabbing headache
339.89 – Other specified headache syndromes
346.00 – Migraine with aura, without mention of intractable migraine without mention of status migrainosus
346.01 – Migraine with aura, with intractable migraine, so stated, without mention of status migrainosus
346.02 – Migraine with aura, without mention of intractable migraine with status migrainosus
346.03 – Migraine with aura, with intractable migraine, so stated, with status migrainosus
346.10 – Migraine without aura, mention of intractable migraine without mention of status migrainosus
346.11 – Migraine without aura, with intractable migraine, so stated, without mention of status migrainosus
346.12 – Migraine without aura, without mention of intractable migraine with status migrainosus
346.13 – Migraine without aura, with intractable migraine, so stated, with status migrainosus
346.20 – variants of migraine, not elsewhere classified, without mention of intractable migraine without mention of status migrainosus
346.21 – Variants of migraine, not elsewhere classified, with intractable migraine, so stated without mention of status migrainosus
346.22 – Variants of migraine, not elsewhere classified, without mention of intractable migraine with status migrainosus
346.23 – Variants of migraine, not elsewhere classified, with intractable migraine, so stated with status migrainosus
346.30 – Hemiplegic migraine, without mention of intractable migraine without mention of status migrainosus
346.31 – Hemiplegic migraine, with intractable migraine, so stated, without mention of status migrainosus
346.32 – Hemiplegic migraine, without mention of intractable migraine with status migrainosus
346.33 – Hemiplegic migraine, with intractable migraine, so stated, with status migrainosus
346.40 – Menstrual migraine, without mention of intractable migraine without mention of status migrainosus
346.41 – Menstrual migraine, with intractable migraine, so stated, without mention of status migrainosus
346.42 – Menstrual migraine, without mention of intractable migraine with status migrainosus
346.43 – Menstrual migraine, with intractable migraine, so stated, with status migrainosus
346.50 – Persistent migraine aura without cerebral infarction, without mention of intractable migraine without mention of status migrainosus
346.51 – Persistent migraine aura without cerebral infarction, with intractable migraine, so stated, without mention of status migrainosus
346.52 – Persistent migraine aura without cerebral infarction, without mention of intractable migraine with status migrainosus
346.53 – Persistent migraine aura without cerebral infarction, with intractable migraine, so stated, with status migrainosus
346.60 – Persistent migraine aura with cerebral infarction, without mention of intractable migraine without mention of status migrainosus
346.61 – Persistent migraine aura with cerebral infarction, with intractable migraine, so stated, without mention of status migrainosus
346.62 – Persistent migraine aura with cerebral infarction, without mention of intractable migraine with status migrainosus
346.63 – Persistent migraine aura with cerebral infarction, with intractable migraine, so stated, with status migrainosus
346.70 – Chronic migraine without aura, without mention of intractable migraine without mention of status migrainosus
346.71 – Chronic migraine without aura, with intractable migraine, so stated, without mention of status migrainosus
346.72 – Chronic migraine without aura, without mention of intractable migraine with status migrainosus
346.73 – Chronic migraine without aura, with intractable migraine, so stated, with status migrainosus
346.80 – Other forms of migraine, without mention of intractable migraine without mention of status migrainosus
346.81 – Other forms of migraine, with intractable migraine, so stated, without mention of status migrainosus
346.82 – Other forms of migraine, without mention of intractable migraine with status migrainosus
346.83 – Other forms of migraine, with intractable migraine, so stated, with status migrainosus
346.90 – Migraine, unspecified without mention of intractable migraine without mention of status migrainosus
346.91 – Migraine, unspecified, with intractable migraine, so stated, without mention of status migrainosus
346.92 – Migraine, unspecified, without mention of intractable migraine with status migrainosus
346.93 – Migraine, unspecified, with intractable migraine, so stated, with status migrainosus
723.1 – Cervicalgia
723.2 – Cerviocranial syndrome
723.8 – Other syndromes affecting cervical region
784.0 – Headache

CPT Codes
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
64575 – Incision for implantation of neurostimulator electrodes; peripheral nerve (excludes sacral 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
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
References: