Occipital Nerve Stimulation

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DESCRIPTION

Various treatments have been advocated for headaches (migraine and non-migraine) and occipital neuralgia. Oral analgesics and anti-inflammatory agents are effective for some individuals, but there is a population of individuals who do not experience pain relief with these medications. For those individuals who are not responsive to initial therapies other treatment modalities to include occipital nerve stimulation (ONS) have been investigated in the treatment of these conditions.

Occipital nerve stimulation is a form of neuromodulation that is reversible and adjustable and can be tailored to an individual's specific needs. However, the mechanisms of action for the paresthesia patterns and pain relief obtained from an occipital nerve stimulation (ONS) is not completely understood. 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.

Prior to permanent implantation, a trial is performed in which leads are placed under the skin and are connected to an external battery. The trial period is typically 4-7 days and the individual keeps a detailed pain diary. A permanent device is considered only if the individual reports significant improvements in pain and quality of life.

Headache
There are four types of headache:

- vascular
- muscle contraction (tension)
- traction
- 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. One- year prevalence of migraine ranges from 6%–15% in adult men and from 14%–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 behavioral therapy, physical therapy, lifestyle modification (good sleep hygiene, routine meal schedules, regular exercise), and avoidance of migraine triggers. Sumatriptan is commonly used for relief of symptoms. Drugs used to prevent migraine include amitriptyline, propranolol, and other beta-blockers, topiramate and other antiepileptic drugs, and verapamil.

Hemicrania continua: Hemicrania continua 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 occurs mainly in woman, and its true prevalence is not known. Indomethacin usually provides rapid relief of symptoms. Other NSAIDs, including ibuprofen, celecoxib, and naproxen, can provide some relief from symptoms. Amitriptyline and other tricyclic antidepressants are effective in some individuals.

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 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 one or two 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 1.0/1,000. Management of cluster headache consists of abortive and preventive treatment. Abortive treatments include subcutaneous injection or intranasal sumatriptan, or topical anesthetics sprayed into the nasal cavity. Some individuals 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.

Migraine Headache

Clinical Context and Purpose
The purpose of occipital nerve stimulation in individuals who have migraines is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest are individuals with migraine headaches.

Intervention
The therapy being considered is occipital nerve stimulation.
The occipital nerve stimulation device is implanted by a physician trained in the procedure, such as a neurologist, in an outpatient clinical setting.

Comparators
Comparators of interest include medication and self-management (e.g., relaxation, exercise), which are prescribed by general practitioner physicians or neurologists in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life (QOL) and treatment related morbidity. Based on the available literature, follow-up of 12 weeks to 1 years is recommended.

Two systematic reviews of the literature on occipital nerve stimulation (ONS) were published in 2015. Both included RCTs and observational studies. The trial by Chen et. al. identified 5 RCTs and 7 case series with at least 10 patients. Three of the RCTs were industry-sponsored, multicenter, parallel-group trials and 2 were single-center crossover trials. All five included a sham control group and one trial also included a medication management group. Risk of bias was judged to be high or unclear for all trials. Meta-analyses were performed on 2 outcomes. A pooled analysis of 2 trials did not find a significant difference in response rates between active and sham stimulation (relative risk

[RR], 2.07; 95% confidence interval [CI], 0.50 to 8.55; p=0.31) and a pooled analysis of 3 trials showed a significantly greater reduction in the number of days with prolonged moderate-to-severe headache (mean difference, 2.59; 95% CI, 0.91 to 4.27; p=0.003).

In their systematic review, Yang et. al. (2015) identified the same 5 RCTs as Chen. The Yang review only included studies conducted with patients who had migraines for at least 6 months in duration who did not respond to oral medications. In addition to the RCTs, 5 case series met the inclusion criteria. Yang did not pool study findings. The definition of response rate varied across studies and could include frequency and/or severity of headaches. Response rates in 3 case series with self-reported efficacy were 100% in each, and response rates in the other 2 series were 50% and 89%, respectively. Complication rates in the series ranged from 40% to 100%. Reviewers noted that the case series were subject to biases (e.g, inability to control for the placebo effect), that RCT evidence was limited, and that complication rates were high. The most common complications were lead migration (21% of patients) and infection (7% of patients).

The 2 parallel-group RCTs published as full-text journal articles are detailed next. The Occipital Nerve Stimulation for the Treatment of Intractable Chronic Migraine Headache (ONSTIM) trial was a multicenter, randomized feasibility study of occipital nerve stimulation (ONS) for treatment of intractable chronic migraine headache refractory to preventive medical management. The trial reported by Saper et. al. (2011) evaluated study design and had no primary end point. One hundred ten patients were enrolled, and patients who had a positive response to a short-acting occipital nerve block were randomized as follows: 33 to adjustable stimulation, 17 to preset stimulation of 1 min/d, and 17 to medical management. At the 3-month evaluation, the response rate (percentage of patients who achieve ≥50% reduction in number of headache days per month or a ≥3-point reduction in average overall pain intensity vs baseline) was 39% in the adjustable stimulation group, 6% in the preset stimulation group, and 0% in the medical management group. Twelve (24%) of 51 subjects who had successful ONS device implantation experienced lead migration and 3 (6%) of the 51 subjects were hospitalized for adverse events (infection, lead migration, nausea). Study limitations included a short observation period and ineffective blinding of subjects and investigators to treatment groups.

An industry sponsored, double blind trial, regulated by the U.S. Food and Drug Administration and reported by Silberstein et. al. (2012), randomized 157 patients with chronic migraine refractory to preventative medical management in a 2:1 ratio to active or sham stimulation. Intention-to-treat (ITT) analysis revealed no significant difference between groups in the percentage of patients who achieved 50% or greater reduction in visual analog scale scores for pain at 12 weeks (active 17.1%; control 13.5%). More patients in the occipital nerve stimulation (ONS) group had fewer days with headache, less migraine-related disability, and greater pain relief, although benefits were modest. The most common adverse event was persistent implant site pain. Results from the 52-week open label extension of this trial were published in 2015. Results were reported for the ITT population and for the 125 patients who met selection criteria for intractable

chronic migraine. Twenty-four patients were excluded from analysis due to explanation of the ONS system (n=18) or loss to follow-up. Mean headache days at baseline were 21.6 for the ITT population and 24.2 for the intractable chronic migraine group. In the ITT population, headache days were reduced by 6.7 days, and a reduction of 50% or more in the number of headache days and/or pain intensity was observed in 47.8% of this group. Seventy percent of patients experienced at least 1 of 183 device-related adverse events, of which 8.6% of events required hospitalization and 4.7% of events required surgical intervention. Eighteen percent had persistent pain and/or numbness with the device.

In 2018, Cadalso et. al. conducted a systematic review with meta-analysis on the efficacy of occipital nerve stimulation (ONS) in reducing the intensity, duration, and frequency of medically intractable primary headaches. A systematic review was carried out by searching three electronic databases: the Cochrane Library, MEDLINE via PubMed, and Web of Science. Randomized controlled trials (RCTs) and case series were eligible for inclusion. RCTs were assessed for quality of evidence by using the Cochrane Risk of Bias and the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) tools. Descriptive statistics of reported outcomes in eligible studies are presented in tabular form. Meta-analyses of RCTs comparing ONS therapy to sham therapy in chronic migraine patients were conducted for the outcomes responder rate, headache frequency, and headache intensity. Four RCTs, 1 follow-up study, and 19 case series met the inclusion criteria. The quality of the evidence was low, with all four RCTs assessed as having a high risk of bias and small sample size. Meta-analyses of three RCTs showed patients receiving ONS therapy had a significant reduction of 3 headache days per month (difference in means = -3.061; 95% confidence interval [CI] = -5.162 to -0.961; P = .004) and a significant reduction in Migraine Disability Assessment score (standardized difference in means [SDM] = -0.634; 95% CI = -0.933 to -0.335; P < .001) compared to sham (subthreshold) therapy. There were no statistically significant differences in reduction in pain intensity (SDM = -1.220; 95% CI = -2.489 to -0.049; P = .060) or in the number of responders (risk ratio [RR] = 1.581; 95% CI = 0.749 to 3.355; P = .229). The authors concluded, occipital nerve stimulation (ONS) may be effective when compared to sham therapy, but the small number of RCTs and the heterogeneity of outcomes suggest further research in the field is needed.

In 2020, Moisset et. al., performed a systematic review and meta-analysis of randomized controlled trials (RCTs) focusing on migraine treatment using neurostimulation methods. Thirty-eight articles were included in the qualitative analysis (7 acute, 31 preventive) and 34 in the quantitative evaluation (6 acute, 28 preventive). Remote electrical neuromodulation (REN) was effective for acute treatment. Data were insufficient to draw conclusions for any other techniques (single studies). Invasive occipital nerve stimulation (ONS) was effective for migraine prevention, with a large effect size but considerable heterogeneity, whereas supra-orbital transcutaneous electrical nerve stimulation (TENS), percutaneous electrical nerve stimulation (PENS), and high-frequency repetitive transcranial magnetic stimulation (rTMS) over the primary motor cortex (M1) were effective, with small to medium effect sizes. Vagus nerve stimulation, left prefrontal

cortex rTMS, and cathodal transcranial direct current stimulation (tDCS) over the M1 had no significant effect and heterogeneity was high. Larger well-conducted studies are still necessary for most to confirm their efficacy and determine their true effect sizes.

In a Hayes Technology Assessment August 2021 regarding the use of occipital nerve stimulation (ONS) for the treatment of chronic migraine (CM) in individuals who have failed to respond to conservative management. Currently there is not enough evidence to establish definitive criteria for patient selection for ONS. This is due to lack of consistent definition on refractory or intractable chronic migraine and an inadequate description of patient demographics and clinical characteristics such as comorbidities that may affect the response to ONS. While results of this review may suggest that ONS may have a positive effect in some individuals with CM, the heterogeneity in study designs and limitations in study execution in some studies pose challenges in reaching definitive conclusions. Further randomized controlled trials (RCTs) are needed. The Food and Drug Administration (FDA) has not cleared or approved any occipital nerve stimulation (ONS) device for headaches and would be considered an off-label use.

Section Summary
Current literature includes systematic reviews, randomized controlled trials (RCTs) and case series. Findings from pooled analyses of randomized controlled trials (RCTs) were mixed. For example, compared with sham stimulation, response rates (i.e., $\geq$ 50% reduction in VAS score) for occipital nerve stimulation (ONS) did not differ significantly, but the number of days with prolonged moderate-to-severe headache was reduced in individuals with chronic migraines (CM). ONS was also associated with a substantial number of minor and serious adverse events. A Hayes Technology Assessment August 2021 found results that may suggest ONS may have a positive effect in some individuals with CM, however, the heterogeneity in study designs and limitations in study execution in some studies pose challenges in reaching definitive conclusions. Further randomized controlled trials (RCTs) are needed. The Food and Drug Administration (FDA) has not cleared or approved any occipital nerve stimulation (ONS) device for headaches and would be considered an off-label use.

Non-Migraine Headaches

Clinical Context and Test Purpose
The purpose of occipital nerve stimulation in individuals who have non-migraine headaches is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is individuals with non-migraine headache.

Intervention
The therapy being considered is occipital nerve stimulation.

The occipital nerve stimulation is implanted by a physician trained in the procedure, such as neurologist in an outpatient clinical setting.

Comparators
Comparators of interest include medication and self-management (e.g., relaxation, exercise), which are prescribed by general practitioner physicians or neurologists in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life and treatment related morbidity. Based on the available literature, follow-up of 12 weeks to 1 years is recommended.

Hemicrania Continua
The evidence evaluating the use of occipital nerve stimulation (ONS) for hemicranias continua is limited and consists of a small crossover study by Burns et al (2008) who reported on the efficacy of continuous unilateral ONS in 6 patients. Pain on a 10-point scale was recorded hourly in-patient pain diaries, and the Migraine Disability Assessment was administered at each follow-up visit. Four of 6 patients reported substantially less pain (range, 80%-95% less), 1 reported 30% less pain, and 1 reported 20% worse pain. Adverse events were mild and associated with transient overstimulation.

Cluster headache

In a Hayes Technology Assessment (annual review completed November 1, 2021) regarding occipital nerve stimulation (ONS) for the treatment of chronic cluster headaches that failed conservative management found the evidence to be small in size, very low in quality (lack of studies with placebo control) and the reviewed studies provide insufficient evidence in the effectiveness of ONS for the treatment of chronic cluster headaches.

In 2021, Leplus et. al., evaluated occipital nerve stimulation long-term efficacy in refractory chronic cluster headache (rCCH). One-hundred five (105) patients were studied with rCCH, treated by ONS within a multicenter ONS prospective registry. Efficacy was evaluated by frequency, intensity of pain attacks, quality of life (QoL) EuroQol 5 dimensions (EQ5D), functional (Headache Impact Test-6, Migraine Disability Assessment) and emotional (Hospital Anxiety Depression Scale [HAD]) impacts, and medication consumption. At last follow-up (mean 43.8 months), attack frequency was reduced >50% in 69% of the patients. Mean weekly attack frequency decreased from 22.5 at baseline to 9.9 ($P < .001$) after ONS. Preventive and abortive medications were significantly decreased. Functional impact, anxiety, and QoL significantly improved after ONS. In excellent responders (59% of the patients), attack frequency decreased by 80% and QoL (EQ5D visual analog scale) dramatically improved from 37.8/100 to 73.2/100. When comparing baseline and 1-yr and last follow-up outcomes, efficacy was sustained over time. In multivariable analysis, low preoperative HAD-depression score was correlated to a higher risk of ONS failure. During the follow-up, 67 patients experienced

at least one complication, 29 requiring an additional surgery: infection (6%), lead migration (12%) or fracture (4.5%), hardware dysfunction (8.2%), and local pain (20%).

Several case series assessing cluster headache were identified, with sample sizes ranging from 10 to 67 patients. In 2016, Fontaine et. al. published a prospective case series of 67 patients with chronic cluster headache (CCH). Data were taken from a French database on occipital nerve stimulation (ONS) for treating refractory headache disorders. Sixty-seven patients with CCH were included in the database; data were available for 52 (78%) patients at 3 months and 44 (66%) patients at 12 months. The primary outcome was a composite score that incorporated patient's global impression of change, reduction in the frequency of headache attacks, and changes in prophylactic medications. For patients with available data, at 3 months, 34 (65.4%) of 52 were considered to be excellent responders, 9 (17.3%) of 52 were mild responders, and 9 (17.3%) of 52 were non-responders. At 12 months, 22 (48%) of 44 were excellent responders, 10 (21.7%) of 44 were mild responders, and 15 (32.6%) of 44 were non-responders. The series had a large amount of missing data at follow-up.

In 2016, Leone et. al. published a case series of occipital nerve stimulation (ONS) in 35 patients with chronic cluster headache (CCH). This series had the longest follow-up (median, 6.1 years; range, 1.6-10.7 years). Selection criteria included daily or almost daily cluster headache attacks in the past year and resistance of prophylactic drugs. Twenty (66.7%) of the 30 patients in the per protocol analysis had 50% or more reduction in headache number per day and were considered responders. In 12 (40%) patients, improvement was considered stable (i.e., ≤3 headache attacks per month). Limitations of the series reporting on cluster headaches included lack of blinding and comparison groups.

Headache Associated with Chiari Malformation

Vadivelu et. al. (2012) reported on a case series of 22 patients with Chiari malformation and persistent occipital headaches. Of the 22, 15 (68%) had a successful occipital neurostimulator trial and underwent permanent implantation. At a mean follow-up at 18.9 months (range 6-51 months), 13 (87%) of the 15 patients reported pain relief greater than 50%. Forty percent of patients reported device related complications requiring additional surgery (lead migration, uncomfortable position of generator, wound infection) during follow-up.

Occipital Neuralgia

Pain in the occipital-cervical area can originate from any structure in the posterior scalp and neck: muscles, joints, ligaments, connective tissue, blood vessels and of course nerves. If the occipital nerves are the cause, then the syndrome is called occipital neuralgia. Neuralgia is a form of neuropathic pain.

The occipital nerves are two paired nerves (right and left) that supply sensation to the posterior scalp, from the crown of the head, down to the top portion of the neck. The occipital nerves originate from posterior branches of the C2 nerve root. The nerve courses

just beneath the arch of the C1 vertebrae, in close proximity to vertebral venous structures, the adjacent atlantoaxial ligament and cervical facet joint. It passes through the semispinalis muscle, and then through the region where the trapezius muscle attaches to the occipital bone. From there, branches of the nerve fan out to innervate the posterior scalp.

Occipital neuralgia can be considered a primary headache disorder, or a secondary headache disorder. The International Headache Society defines primary occipital neuralgia as "a paroxysmal jabbing pain in the distribution of the greater or lesser occipital nerves or of the third occipital nerve, sometimes accompanied by diminished sensation or dysaesthesia in the affected area. It is commonly associated with tenderness over the nerve concerned." To meet criteria for occipital neuralgia the pain must meet the following criteria:

- Paroxysmal stabbing pain, with or without persistent aching between paroxysms, in the distribution(s) of the greater, lesser and/or third occipital nerves.
- Tenderness over the affected nerve.
- Pain is eased temporarily by local anesthetic block of the nerve.

Occipital nerve block (usually a mixture of local anesthetic plus a glucocorticoid) is usually the treatment of choice for occipital neuralgia. Some other modalities that may be used include physical therapy; acupuncture; massage therapy; chiropractic treatments; anti-inflammatory medications; muscle relaxants; anticonvulsants; anti-depressants; other percutaneous blocks such as facet joint blocks, medical branch blocks and transforaminal epidural steroid injections; radiofrequency ablation and occipital nerve stimulation (ONS). Occipital nerve stimulation has been investigated in selected cases of severe occipital neuralgia unresponsive to less invasive measures.

A 2015 systemic review by Sweet et. al. identified 9 small case series (< 15 patients each) assessing the efficacy of occipital nerve stimulation for treating medically refractory occipital neuralgia. Reviewers did not pool study findings. Conclusions cannot be drawn on the impact of occipital nerve stimulation (ONS) on occipital neuralgia due to the lack of randomized controlled trials (RTCs) or other controlled studies.

Section Summary
The evidence on occipital nerve stimulation (ONS) consists of case series; no randomized controlled trials (RCTs) or nonrandomized comparative studies were identified. Many of the case series were small; series with over 25 patients were available only for treatment of cluster headache. Although case series tended to find a substantial number of patients improved after ONS, the studies lacked blinding and comparison groups. RCTs are needed to assess outcomes between ONS and comparators (e.g., control for potential placebo effect).

Summary of Evidence
For individuals who have chronic migraine (CM) headaches refractory to preventative medical management who receive occipital nerve stimulation (ONS), the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and observational studies/case series. Currently there is not enough evidence to establish definitive criteria for patient selection for ONS. This is due to lack of consistent definition on refractory or intractable chronic migraine and an inadequate description of patient demographics and clinical characteristics such as comorbidities that may affect the response to ONS. While results of the current literature may suggest that ONS may have a positive effect in some individuals with CM, the heterogeneity in study designs and limitations in study execution in some studies pose challenges in reaching definitive conclusions. Further randomized controlled trials (RCTs) are needed. The Food and Drug Administration (FDA) has not cleared or approved any occipital nerve stimulation (ONS) device for headaches and would be considered an off-label use. The evidence is insufficient to determine the effects of the technology on net health outcomes.

For individuals who have non-migraine headaches (e.g., hemicranias continua, cluster headache, headache associated with Chiari malformation or occipital neuralgia) who received occipital nerve stimulation (ONS), the evidence includes case series. 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 ONS, these studies lacked blinding and comparison groups. RCTs are needed to compare outcomes between ONS and comparators (e.g., to control for a potential placebo effect). The evidence is insufficient to determine the effects of the technology on net health outcomes.

Other Indications
Fibromyalgia
Fibromyalgia is a chronic pain disorder that is often difficult to treat. The treatment of fibromyalgia is directed at reducing the major symptoms of this disorder, including chronic widespread pain, fatigue, insomnia, and cognitive dysfunction. Interventions include several non-pharmacologic and pharmacologic therapies that are often provided in combination. Many individuals experience continued symptoms despite initial non-pharmacologic and pharmacologic therapies. Occipital nerve stimulation (ONS) has been studied for the treatment of fibromyalgia in adults not responsive to initial therapies. Several trials have evaluated the effect of occipital nerve stimulation (ONS), while some of the results were positive, the trials were small and not well-controlled.

Summary of Evidence
For individuals with fibromyalgia who receive occipital nerve stimulation (ONS) the available studies are limited making it difficult to draw conclusions regarding the efficacy of occipital nerve stimulation for the treatment of fibromyalgia. There are no well-designed randomized controlled studies in the medical literature comparing occipital nerve stimulation (ONS) to established treatment options. Further randomized controlled clinical trials (RCTs) are needed to include larger patient populations with longer follow-

up to establish the benefits of occipital nerve stimulation (ONS) for the treatment for this condition. The evidence is insufficient to determine the effects of occipital nerve stimulation on net health outcomes for the treatment of fibromyalgia.

Practice Guidelines and Position Statements:

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

Level III recommendation: evidence from case series, comparative studies with historical controls, case reports, and expert opinion, as well as significantly flawed, controlled trials.

National Institute for Health and Care Excellence (NICE)
2013 Guidance from the National Institute for Health and Care Excellence (NICE) states: "That the evidence on occipital nerve stimulation (ONS) for intractable chronic migraine shows some efficacy in the short term but there is very little evidence about long term outcomes. Regarding 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."

Regulatory Status
Currently, there are no occipital nerve stimulation devices approved or cleared for marketing by the U.S. Food and Drug Administration (FDA) for the treatment of headache or occipital neuralgia. Occipital nerve stimulation continues to represent an off-label use.

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policies:

- 07.01.59 Deep Brain Stimulation
- 01.01.23 Electrical Stimulation for the Treatment of Muscle Rehabilitation, Pain and Miscellaneous Conditions
- 07.01.60 Vagus Nerve Stimulation

Occipital nerve stimulation (ONS) is considered **investigational** for all indications.

Based on review of the current peer reviewed medical literature the available studies are limited and have significant methodological flaws, making it difficult to draw conclusions regarding the efficacy of occipital nerve stimulation (ONS) for the treatment of chronic headaches (migraine and non-migraine headaches [e.g., hemicranias continua, cluster headache, headache associated with Chiari malformation or occipital neuralgia]), fibromyalgia, and any other indications. There are no well-designed randomized controlled studies in the medical literature comparing occipital nerve stimulation to established treatment options. Further randomized clinical trials (RCTs) with greater number of individuals and longer follow up are needed to establish the benefits of occipital nerve stimulation. The evidence is insufficient to determine the effects of this technology on net health outcomes.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 61885 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
- 61886 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
- 64553 Percutaneous implantation of neurostimulator electrodes; cranial nerve
- 64555 Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
- 64575 Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
- 64568 Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
- 64569 Revision or replacement of cranial nerve (eg vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
- 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
- C1767 Generator neurostimulator (implantable) non-rechargeable
- C1778 Lead, neurostimulator
- C1787 Patient programmer, neurostimulator
- C1816 Receiver and/or transmitter neurostimulator (implantable)
- C1820 Generator neurostimulator (implantable), non high-frequency with rechargeable battery and charging system

- C1822 Generator neurostimulator (implantable, high frequency with rechargeable battery and charging system
- C1897 Lead neurostimulator test kit (implantable)
- L8679 Implantable neurostimulator, pulse generator any type
- L8680 Implantable neurostimulator electrode, each
- L8681 Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
- L8682 Implantable neurostimulator radiofrequency receiver
- L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
- L8685 Implantable neurostimulator pulse generator, single array, rechargeable includes 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

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POLICY HISTORY

Date	Reason	Action
June 2022	Annual Review	Policy Renewed
June 2021	Annual Review	Policy Renewed
June 2020	Annual Review	Policy Renewed
June 2019	Annual Review	Policy Renewed
June 2018	Annual Review	Policy Revised
June 2017	Annual Review	Policy Revised
June 2016	Annual Review	Policy Renewed
July 2015	Annual Review	Policy Revised
February 2015		Policy Revised
August 2014	Annual Review	Policy Revised
September 2013	Annual Review	Policy Renewed
October 2012	Annual Review	Policy Renewed
October 2011	Annual Review	Policy Renewed

August 2010	Inquiry	New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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