ASURIS NORTHWEST HEALTH

Medical Policy Manual Surgery, Policy No. 174

Occipital Nerve Stimulation

Effective: April 1, 2024

Next Review: February 2025
Last Review: February 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

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) 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.

MEDICAL POLICY CRITERIA

Occipital nerve stimulation is considered **investigational** for all indications, including but not limited to headaches.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Interferential Current Stimulation, Durable Medical Equipment, Policy No. 83.07
2. Sphenopalatine Ganglion Block for Headache and Pain, Medicine, Policy No. 160
3. Spinal Cord Stimulation, Surgery, Policy No. 45
4. Implantable Peripheral Nerve Stimulation for Chronic Pain of Peripheral Nerve Origin, Surgery, Policy No. 205

BACKGROUND

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.

There are four 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 three months. An estimated 45 million Americans experience chronic headaches. For at least half of these people, the problem is severe and sometimes disabling.

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% to15% in adult men and from 14% to35% 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, 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 occurs mainly in women, and its true prevalence is not known. Indomethacin usually provides rapid relief of symptoms. Other nonsteroidal anti-inflammatories (NSAIDs), including ibuprofen, celecoxib, and naproxen, can provide some relief from symptoms. Amitriptyline and other tricyclic antidepressants are effective in some patients.

Cluster headache is a vascular headache that 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 eight 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 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.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has not yet cleared any occipital nerve stimulation device for treatment of headache.

The Synergy™ IPG (implantable pulse generator) device from Medtronic received marketing clearance in 1999 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 the FDA for spinal cord stimulation and has received CE mark approval in Europe for the treatment of chronic migraines.

EVIDENCE SUMMARY

The principal outcomes associated with treatment of headache are relief of pain, return to work, and improved functional level. Relief of pain can be a subjective outcome associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCT) are required to control for the placebo effect and determine whether any treatment effect provides a significant advantage.

The technology must also be evaluated in general groups of patients against existing treatments. In patients with mild to moderate symptoms, occipital nerve stimulation may be compared to other forms of conservative therapy such as topical anesthetics, rest, or non-steroidal anti-inflammatory or migraine medications.

Therefore, the focus of the evidence summary is on RCTs comparing occipital nerve stimulation (ONS)-treated patients with those in a sham treatment or standard of care group.

SYSTEMATIC REVIEWS

Membrilla (2023) published a systematic review and meta-analysis to evaluate the effectiveness of pharmacologic and non-pharmacologic interventions in preventative treatment of chronic cluster headache (CCH) for people who do not respond to conventional therapy.[1] Studies were included if at least a portion of the participants met European Headache Federation diagnostic criteria for refractory CCH (rCCH), and if the reported outcome was reduced attack frequency. The review included a total of 45 studies, of which 12 were of ONS. Wilbrink (2021), as detailed below, was the only RCT on ONS. The meta-analysis also included the following studies that are cited below: Diaz-de-Teran (2021), Leplus (2021), and Magis (2011).[2-5] The pooled response rate from the 12 ONS studies was 57.3% (odds ratio [OR] 0.573, 95% confidence interval [CI] 0.481-0.665, I^2=68.45, p<0.001). Of the 45 studies included in the review only 7 were RCTs. While the authors concluded the available evidence supported the use of ONS, its harms were minimized (“these adverse events will likely be less prevalent because of technical advances”). The study noted that the overall analysis had high heterogeneity of interventions, study designs, and response measures, and most evidence was rated as having moderate to serious risk of bias.

As part of a consensus development process Barad (2022) published the results of a systematic review of studies on percutaneous strategies for migraine intervention.[6] This review included four randomized controlled trials (RCTs) on implantable ONS (Serra 2012, Slotty 2015, Silberstein 2012, and Saper 2011). An additional publication (Mekhail (2017) was excluded, as it was a subgroup analysis of the Silberstein cohort. The overall strength for the certainty of evidence for reduction of headache days was moderate with a moderate effect size. The strength of certainty of evidence for reduction in acute medication use was very low with a low, nonsignificant effect size. The strength of certainty of evidence for impairment as related to patient-related outcomes was moderate at 12 weeks with a moderate effect size.

Implantable ONS had significantly more adverse events that other interventional therapies examined. The recommendation was “weak” for the potential net benefit of implantable ONS for chronic migraine prevention.

Occipital nerve stimulation was addressed in the Comparative Effectiveness Review of Interventional Treatments for Acute and Chronic Pain that was prepared for the Agency for Healthcare Research and Quality (AHRQ) by the Pacific Northwest Evidence-Based Practice Center (2021).[7] The review assessed three studies, Saper (2011), Serra (2012), Silberstein (2012), and focused on the following outcomes: pain, function, number of days with headache, and mood state.[8-10] There was insufficient evidence to assess ONS compared to sham treatment for headache. While there was evidence of a reduction in headache pain, headache days, and disability at 3 months vs. usual care, the difference was not statistically significant ($p>0.05$). The review found evidence of harm from ONS, most often from lead migration that occurred in 14-24% of patients in the assessed studies, and one trial reported a 5.9% rate of device-related serious adverse events that required hospitalization.

Patel (2021) published a systematic review (SR) of data from RCTs on electrical nerve stimulation modalities, including occipital nerve stimulation (ONS), in the treatment of migraine.[11] Although 16 studies were included in the review, only three (Mekhail 2017, Dodick 2015, and Slotty 2015) were studies of ONS. Studies were rated low risk of bias in most domains, however, the authors note two of the ONS studies had “unknown” risk of bias due to open-label study design or high occurrence of adverse events. No pooled or quantitative comparisons for any outcomes were reported for any of the modalities.

A SR with meta-analysis of neuromodulation for acute and preventative migraine treatment was published by Moisset (2020).[12] This broad review included three studies of invasive ONS, all investigating its use for the treatment of chronic migraine. Only one of the identified studies was of high quality (Silbertstein 2012) which, as discussed below, did not identify a significant effect of the intervention on the primary outcome, although positive effects were found for secondary outcomes. The other two trials included in the review (Saper 2011 and Serra 2012) were low and moderate quality due to risk of biases in selective reporting, sample calculation, statistical methods, and/or blinding. Outcomes of the meta-analysis favored a positive effect of invasive ONS, with a large effect size (-1.090; 95%CI: -1.977 to -0.204) however high heterogeneity between studies ($I2 = 88\%$) was reported. Ultimately, the authors conclude that larger well-conducted studies are needed to confirm treatment efficacy and determine true effect sizes.

Cadalso (2017) published a systematic review (SR) evaluating the impact occipital nerve stimulation had on healthcare outcomes, for intractable primary headache disorders.[13] The SR included four RCTs, one follow-up study, and 19 case series. The authors stated that although the RCTs showed a decrease in headache frequency and improved migraine disability assessment scores, ONS did not improve pain intensity and there was heterogeneity of outcomes. In addition, the RCTs had small sample sizes and risk of bias.

Yang (2016) identified the same five RCTs as the 2015 SR by Chen, summarized below.[14] The Yang review only included studies conducted with patients with migraine of at least six months in duration who did not respond to oral medications. In addition to the RCTs, five case series met the inclusion criteria. Yang et al 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 three case series with self-reported efficacy were 100% each, and response

rates in the other two series were 50% and 89%, respectively. Complication rates in the series ranged from 40% to 100%. The authors 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.

Two SRs of the literature on occipital nerve stimulation (ONS) were published in 2015. Both included RCTs and observational studies. Chen identified five RCTs and seven case series with at least 10 patients.[15] Three of the RCTs were industry-sponsored, multicenter, parallel-group trials and two 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 two outcomes. A pooled analysis of 2 studies did not find a significant difference in response rate between active and sham stimulation (risk ratio [RR], 2.07; 95% confidence interval [CI], 0.50 to 8.55; p=0.31) and a pooled analysis of three studies 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. Sweet (2015) published a SR that identified nine small case series (<15 patients each) assessing the efficacy of ONS for treating medically refractory occipital neuralgia.[16] The authors did not pool study findings. No conclusions can be drawn about the impact of ONS on occipital neuralgia due to the lack of RCTs or other controlled studies.

The National Institute for Health and Care Excellence (NICE, 2013) evaluated two RCTs and one case series to determine if ONS was effective in decreasing headache frequency, duration and severity.[17] Both RCTs compared ONS with sham stimulation at three months. Although the smaller RCT with 67 patients determined that the ONS group responded better than the sham group, the larger RCT with 157 patients showed no difference in responder rate. NICE concluded that ONS for intractable chronic migraines is efficacious in the short-term, but there is little evidence to indicate long-term outcome effects. NICE stated ONS should only be used for clinical governance, consent, and audit or research.

RANDOMIZED CONTROLLED TRIALS

Wilbrink (2021) published the safety and efficacy data from of a multicenter randomized controlled trial (RCT) of ONS for medically intractable chronic cluster headache (MICCH).[2] This trial is termed the ICON study (ClinicalTrials.gov NCT01151631). Patients were randomized (1:1) to 24 weeks of ONS at either 100% or 30% of the individually determined range between paraesthesia threshold and near-discomfort. Because ONS causes paraesthesia precluding masked comparison to placebo, high-intensity was compared to low-intensity stimulation, which is hypothesized to cause similar paraesthesia but with different efficacy. There were 150 patients enrolled and 131 were randomly assigned to treatment: 65 patients to 100% ONS and 66 to 30% ONS. In weeks 25-48, participants received individually optimized open-label ONS. The primary outcome was the weekly mean attack frequency in weeks 21-24 compared with baseline. In the 100% ONS stimulation group, attack frequency decreased from 17.58 (9.83 to 29.33) at baseline to 9.50 (3.00 to 21.25) at 21-24 weeks (median change from baseline -4.08, -11.92 to -0.25), and for the 30% ONS stimulation group, attack frequency decreased from 15.00 (9.25 to 22.33) to 6.75 (1.50 to 16.50; -6.50, -10.83 to -0.08). The difference in attack frequency between groups at the end of the masked phase in weeks 21-24 was -2.42 (95% CI -5.17 to 3.33). In the masked study phase, 129 adverse events occurred in the 100% ONS group and 95 occurred in the 30% ONS group. Of these, 17 and eight of the adverse events in the 100% and 30% groups, respectively, were considered serious, as they required hospital admission for minor hardware-related issues. The most

common adverse events were local pain, impaired wound healing, neck stiffness, and hardware damage.

Serra and Marchioretto (2012) conducted a crossover RCT in which 30 patients with chronic migraine (100% of patients) and medication overuse headache (85% of patients) were implanted with an ONS and randomized to “Stimulation On” or “Stimulation Off” arms.[9] After one month, or if headaches worsened during the off period, patients were crossed over to the other arm. The mean number of days when patients randomized to the off condition turned on the generators was 4.65 days (range, 1-12 days). Follow-up examinations were conducted at one, three, six, and 12 months after nerve stimulator implantation, during which time the stimulation parameters were adjusted in order to optimize the perception of paresthesia. In addition, the patients were provided with remote controls to modify the stimulation amplitude. At baseline, the average frequency of migraines was 5.8 days per week and the median headache severity was eight on an 11-point numerical rating scale. Headache intensity and/or frequency were significantly lower in the on arm compared to the off arm and decreased from baseline to each follow-up visit in all patients with Stimulation On. For example, the number of headaches decreased from a median of 6.3 days per week in the off phase to 2.1 days per week in the on phase. The median Migraine Disability Assessment (MIDAS) score decreased from 79 at baseline to 10 at 12-month follow-up. Quality of life measured by the SF-36 significantly improved from baseline throughout the follow-up period. Use of triptans decreased from a median of 20 to three doses/month and use of nonsteroidal anti-inflammatory drug (NSAIDs) use decreased from a median of 25.5 to two doses/month. There were two infections (6.7%) and three lead migrations (10%) during the study. This study is limited by the lack of a control group during follow-up and lack of blinding, although blinding of patients may be difficult due to paresthesia with this treatment.

Silberstein (2012) published a RCT of patients diagnosed with chronic migraine (CM), implanted with a neurostimulation device and randomized 2:1 to active (n=105) or sham (n=52) stimulation.[10] Authors defined the primary endpoint as the difference in the percentage of responders (defined as patients that achieved a ≥50% reduction in mean daily visual analog scale scores) in each group at 12 weeks. A significant difference was reported at a secondary endpoint of 30% reduction; however, no difference was reported between groups at the primary endpoint of 50% reduction. At a 30% reduction, significant difference in reduction of number of headaches, migraine-related disability, and direct reports of pain relief were reported compared to the sham group, but it is unknown if these results are clinically meaningful considering researchers did not meet their established primary endpoint of at least a 50% reduction in mean daily analog scores. In addition, the overall treatment effect was low, with only 17.1% of the active group and 13.5% of the control group classified as responders.

Results from the 52-week open-label extension of this study were published in 2014.[18] Results were reported for the intent-to-treat (ITT) population and for the 125 patients who met criteria for intractable chronic migraine. Twenty-four patients were excluded from analysis due to explantation of the system (n=18) or other 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 50% or greater reduction in headache days and/or pain intensity was observed in 47.8% of patients. Sixty-eight percent of patients were satisfied with the headache relief provided by the device. Seventy percent experienced at least one of 183 device-related adverse events, of which 8.6% required hospitalization and 40.7% required surgical intervention. Eighteen percent of patients had persistent pain and/or numbness with the device.

A small industry-sponsored feasibility RCT reported preliminary safety and efficacy data on ONS for treatment of medically intractable chronic migraine (CM).[8] However, the findings from this small (n=110) and very short (follow-up=three months) study must be interpreted with caution due to the exploratory nature of the design:

- The sample size was chosen to gain experience with ONS and the study was not prospectively powered for efficacy evaluation.
- No primary end points were specified at the outset; at three months, a range of efficacy measures were evaluated in comparison to baseline.

Although the findings from this study may provide direction for future research, they do not provide reliable evidence on the clinical utility of ONS. Per the authors, “reliable conclusions regarding efficacy cannot be established on the basis of this study alone.”

NONRANDOMIZED STUDIES

Evidence from nonrandomized studies of occipital nerve stimulation (ONS) for treatment of headaches is considered insufficient due to methodological limitation such as nonrandom allocation of treatment, lack of adequate comparison groups, small sample size, and short-term follow-up, all of which limit conclusions regarding the safety and effectiveness of ONS treatment.[3, 19-21] Of note, several of these nonrandomized studies reported high rates of ONS revision (20-60%)[5, 22, 23] and/or complications (20-60%)[4, 5, 19, 24-26].

PRACTICE GUIDELINE SUMMARY

AMERICAN ACADEMY OF PAIN MEDICINE

A 2022 evidence-based practice guideline from the American Academy of Pain Medicine on percutaneous interventional strategies for the prevention of migraine provides a “weak” recommendation of implantable stimulation (based on studies of occipital nerve stimulation) for chronic migraine prevention.[6] Implantable stimulation was noted to have significantly more adverse events than other percutaneous interventions, contributing to this “weak” recommendation.

AMERICAN SOCIETY OF PAIN AND NEUROSCIENCE

A 2022 consensus-based guideline on the use of implantable peripheral nerve stimulation for treatment of chronic pain states multiple randomized trials have demonstrated benefit of ONS for chronic migraine.[27] The guideline cites Dodick (2014), Mekhail (2017), Saper (2011), and Serra (2012).[8-10, 18]

- Stimulation of occipital nerves may be offered to patients with chronic migraine headache when conservative treatments have failed. The average size for relief of migraine symptoms is modest to moderate (Level I, Grade B).

- There is presently insufficient evidence to recommend stimulation of supraorbital or infraorbital nerves for neuropathic craniofacial pain (Level II-3, Grade C).

CONGRESS OF NEUROLOGICAL SURGEONS

A 2023 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 guideline was jointly funded by Congress of Neurological Surgeons and the Joint Section on Pain of the American Association of Neurological Surgeons/Congress of Neurological Surgeon. The statement had a level III recommendation based on a systematic review of the literature that only included case series with methodological limitations.

SUMMARY

There is not enough research to show that occipital nerve stimulation (ONS) improves net health outcomes for patients with any condition. Clinical guidelines based on research list ONS as a treatment option but consideration of evidence of benefits vs. harm of ONS is inconsistent in the guidelines. Therefore, ONS is considered investigational for all indications, including but not limited to as a treatment of headache.

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CODES

Codes	Number	Description
CPT	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 electrode array; cranial nerve
	64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
	64569	Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
	64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
	64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	64585	Revision or removal of peripheral neurostimulator electrode array
	64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
	64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
	64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure)
	64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
	64999	Unlisted procedure, nervous system
	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulsewidth, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
	95971	;with simple spinal cord, or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter, programming by physician or other qualified health care professional
	95972	;with complex spinal cord, or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
HCPCS	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
	L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month

Codes	Number	Description
	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, non- rechargeable, includes extension
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
	L8689	External recharging system for battery (internal) for use with implantable neurostimulator

Date of Origin: *June 2010*