

07.01.51 Occipital Nerve Stimulation

Original Effective Date: August 2010

Review Date: June 2025

Revised: June 2023

DISCLAIMER/INSTRUCTIONS FOR USE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:

- [01.01.33 Cranial Electrotherapy Stimulation and Auricular Electrostimulation](#)
- [01.01.37 Miscellaneous Electrical Stimulation for the Treatment of Pain](#)
- [07.01.59 Deep Brain Stimulation](#)
- [07.01.60 Vagus Nerve Stimulation \(VNS\) and Vagal Nerve Blocking Therapy](#)

Summary

Description

Occipital nerve stimulation delivers a small electrical charge to the occipital nerve intended 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.

Summary of Evidence

For individuals who have migraine headaches refractory to preventive medical management who receive occipital nerve stimulation, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Systematic reviews identified 5 sham-controlled randomized trials. Findings from pooled analyses of these RCTs were mixed. For example, compared with placebo, response rates to occipital nerve stimulation did not differ significantly but did reduce the number of days with prolonged moderate-to-severe headache. Occipital nerve stimulation was also associated with a substantial number of minor and serious adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have non-migraine headaches (e.g., hemicrania continua, cluster headaches) who receive occipital nerve stimulation, the evidence includes 1 RCT and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. 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 occipital nerve stimulation, these studies lacked blinding and comparison groups. RCTs are needed to compare outcomes between occipital nerve stimulation and comparators (e.g., to control for a potential placebo effect). One blinded RCT assessing electrical dose-controlled stimulation did not find a significant difference between 100% and 30% (sham) stimulation in individuals with refractory chronic cluster headache. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to determine whether occipital nerve stimulation improves the net health outcome in individuals with migraines or non-migraine headaches.

PRIOR APPROVAL

Not applicable.

POLICY

Occipital nerve stimulation (ONS) is considered **investigational** for all indications because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY GUIDELINES

The U.S. Food and Drug Administration (FDA) has not cleared or approved any occipital nerve stimulation device for treatment of headache. This evidence review addresses potential off-label use.

Coding

See the [Codes](#) table for details.

BACKGROUND

Headache

There are 4 types of headaches: vascular, muscle contraction (tension), traction, and inflammatory. Primary (not the result of another condition) chronic headache is defined as headache occurring more than 15 days of the month for at least 3 consecutive months. An estimated 45 million Americans experience chronic headaches. For at least half of these people, the problem is severe and sometimes disabling. Herein, we only discuss types of vascular headache, including migraine, hemicrania continua, and cluster.

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% to 15% in adult men and from 14% to 35% in adult women. Migraine headaches may last a day or more and can strike as often as several times a week or as rarely as once every few years.

Treatment of Migraine

Drug therapy for migraine is often combined with biofeedback and relaxation training. Sumatriptan and other triptans are commonly used for relief of symptoms. Drugs used to prevent migraine include amitriptyline, propranolol and other β -blockers, topiramate and other antiepileptic drugs, verapamil, and calcitonin gene-related peptide (CGRP) inhibitors.

Hemicrania Continua

Hemicrania continua causes moderate and occasionally 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.

Treatment of Hemicrania Continua

Indomethacin usually provides rapid relief of symptoms. Other nonsteroidal anti-inflammatory drugs, including ibuprofen, celecoxib, and naproxen, can provide some relief of symptoms. Amitriptyline and other tricyclic antidepressants are effective in some patients.

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, conjunctival injection, lacrimation, rhinorrhea, and, less commonly, facial blushing, swelling, or sweating. Bouts of 1 headache every other day up 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 by person, but most people have 1 or 2 cluster periods a year. During remission, no headaches occur for months, and sometimes even years. The intense pain is caused by the dilation of blood vessels, which creates pressure on the trigeminal nerve. While this process is the immediate cause of the pain, the etiology is not fully understood. It is more common in men than in women. One-year prevalence is estimated to be 0 to 1 in 1000.

Treatment of Cluster Headache

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.

Peripheral Nerve Stimulators

Implanted peripheral nerve stimulators have been used to treat refractory pain for many years but have only recently been proposed to manage craniofacial pain. Occipital, supraorbital, and infraorbital stimulation have been reported in the literature.

Regulatory Status

The U.S. Food and Drug Administration (FDA) has not cleared or approved any occipital nerve stimulation device for treatment of headache. In 1999, the Synergy™ IPG device (Medtronic), an implantable pulse generator, was approved by the FDA through the premarket approval process for management of chronic, intractable pain of the trunk or limbs, and off-label use for headache is described in the literature. The Genesis™ Neuromodulation System (St. Jude Medical) was approved by the FDA for spinal cord stimulation, and the Eon™ stimulator has received CE mark approval in Europe for the treatment of chronic migraines. In 2017, the AnkerStim™ lead received CE mark approval for intractable chronic cluster headache.

RATIONALE

This evidence review was created in August 2010 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 2025.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the

alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Migraine Headache

Clinical Context and Therapy Purpose

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% to 15% in adult men and from 14% to 35% in adult women. Migraine headaches may last a day or more and can strike as often as several times a week or as rarely as once every few years.

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.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with migraine headache.

Interventions

The therapy being considered is occipital nerve stimulation.

Occipital nerve stimulation delivers a small electrical charge to the occipital nerve intended 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.

Comparators

Comparators of interest include medication and self-management (e.g., relaxation, exercise).

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 year is recommended.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Chen et al (2015) 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 5 included a sham control group and one 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; $p=0.003$).

Yang et al (2016) identified the same 5 RCTs as Chen in their systematic review. 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).

Randomized Controlled Trials

The 2 parallel-group RCTs published as full-text journal articles are detailed next. Saper et al (2011) reported on the Occipital Nerve Stimulation for the Treatment of Intractable Chronic Migraine Headache (ONSTIM) trial, which was a multicenter, randomized feasibility study of occipital nerve stimulation for treatment of intractable chronic migraine headache refractory to preventive medical management. The trial evaluated study design and had no primary endpoint. 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 achieved $\geq 50\%$ 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 occipital nerve stimulation device implantation experienced lead migration and 3 (6%) of the 51 subjects were hospitalized for adverse

events (infection, lead migration, nausea). Trial limitations included a short observation period and ineffective blinding of subjects and investigators to treatment groups.

Silberstein et al (2012) reported on an industry-sponsored, double-blind trial, regulated by U.S. Food and Drug Administration (FDA) that randomized 157 patients with chronic migraine refractory to preventive medical management in a 2:1 ratio to active or sham stimulation. Intention-to-treat (ITT) analysis revealed no significant differences 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 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. Dodick et al (2015) published results from the 52-week open-label extension of this trial. 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 explantation of the occipital nerve stimulation 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 40.7% of events required surgical intervention. Eighteen percent of patients had persistent pain and/or numbness with the device.

Section Summary: Migraine Headache

Two systematic reviews (2015, 2016) each identified 5 sham-controlled randomized trials. One of the systematic reviews also identified 5 case series. Findings from pooled analyses of RCTs were mixed. For example, compared with sham stimulation, response rates (i.e., $\geq 50\%$ reduction in visual analog scale score) for occipital nerve stimulation did not differ significantly, but the number of days with prolonged moderate-to-severe headache was reduced. Occipital nerve stimulation was also associated with a substantial number of minor and serious adverse events.

Non-Migraine Headaches

Clinical Context and Therapy Purpose

The non-migraine headaches included in this evidence review are hemicrania continua and cluster headache. Hemicrania continua causes moderate and occasionally 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.

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, conjunctival injection, lacrimation, rhinorrhea, and, less commonly, facial blushing, swelling, or sweating. Bouts of one headache every other day up 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 by person, but most people have 1 or 2 cluster periods a year. During remission, no headaches occur for months, and sometimes even years. The intense pain is caused by the dilation of blood vessels, which creates pressure on the trigeminal nerve. While this process is the immediate cause

of the pain, the etiology is not fully understood. It is more common in men than in women. One-year prevalence is estimated to be 0 to 1 in 1000.

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

The following PICO was used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is occipital nerve stimulation.

Occipital nerve stimulation delivers a small electrical charge to the occipital nerve intended 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.

Comparators

Comparators of interest include medication and self-management (e.g., relaxation, exercise).

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 year is recommended.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Cluster Headache

Randomized Controlled Trials

Wilbrink and coworkers (2021) reported on the results an international, randomized, double-blind trial (ICON) of electrical dose-controlled occipital nerve stimulation (ONS) in patients with medically intractable chronic cluster headache, defined as at least 4 attacks per week over 12 weeks of baseline observation. Patients non-responsive to at least 3 standard preventive drugs were randomized to 24 weeks of ONS at either 100% (n=65) or 30% (n=65) of the individually determined range between paresthesia and near-discomfort. This study design was utilized to avoid treatment unmasking. After 24 weeks, patients received individually optimized open-label ONS. The primary objective was defined as the reduction in mean attack frequencies in weeks 21-24 compared to baseline across all patients, and if met, to show a difference in treatment effect between the 100% ONS and 30% ONS groups to support a conclusion of causality. In the overall patient population, a median decrease of 5.21 attacks was observed ($p < 0.0001$). No significant difference in mean attack frequencies was observed between 100% and 30% ONS treatment groups (-2.42; 95% CI, -5.17 to 3.33). At the end of the double-blind trial phase, 61% of participants and 59% of neurologists correctly identified treatment assignment. In the open-label extension phase, the mean attack frequency decreased modestly from -5.21 to -5.92 in the overall population. Fifty-nine serious adverse events were reported among 46 subjects. Of these, 35 were reported as hardware-related. One subject suffered a transient ischemic attack 1 month and 15 days after implantation and resumption of anti-thrombotic treatment. This individual had multiple vascular risk factors and the event was deemed unrelated to the device or procedure. The number of serious adverse events was similar in both treatment groups. Given that no significant treatment difference was observed between groups, the investigators concluded that future research should focus on optimizing stimulation protocols and elucidating the underlying mechanism of action.

Brandt et al (2023) published results from the open-label extension phase of the ICON trial. Among the 103 eligible participants, 88 (85%) provided informed consent, and follow-up durations varied: 73 (83%) were tracked for at least two years, 61 (69%) for three years or more, 33 (38%) for at least five years, and 3 (3%) for 8.5 years or longer. The average follow-up period was 4.2 ± 2.2 years. The pooled geometric mean weekly attack frequency showed significant reductions compared to baseline (16.2; 14.4-18.3): 4.2 (2.8-6.3) after one year, 5.1 (3.5-7.6) after two years, and 4.1 (3.0-5.5) after five years. Among those who initially responded to ICON with at least a 50% reduction in attacks (49 out of 88, or 56%), 35 out of 49 (71%) maintained their response. Additionally, 15 out of 39 (38%) of those who initially showed no response later met the $\geq 50\%$ responder criteria for at least half of their follow-up period. A majority of participants (69 out of 88, or 78%) reported a subjective improvement at their last follow-up, and 70 out of 88 (81%) stated they would recommend ONS to others. However, hardware-related surgeries were necessary in 44 out of 88 (50%) participants, occurring in 112 out of 122 (92%) instances (0.35 person-year⁻¹ [0.28-0.41]). No predictive factors for effectiveness were identified.

Systematic Reviews

Membrilla et al (2023) published a systematic review of 11 observational studies and 1 RCT that evaluated occipital nerve stimulation as preventive treatment of refractory chronic cluster headache. The RCT compared occipital nerve stimulation at 100% or 30% of the individually determined range between paresthesia threshold and near-discomfort. Risk of bias was judged to be low for the RCT and moderate or high for the observational studies. Meta-analysis was performed on response rate, which found a

pooled result of 57.3% (95% CI, 0.481-0.665, $I^2 = 68.45$). Interpretation of this finding is limited by the substantial heterogeneity and moderate to high risk of bias, however.

Case Series

Numerous case series assessing cluster headache were identified, with sample sizes ranging from 10 to 105 patients. The largest of these case series included 105 patients with refractory cluster headache in a French occipital nerve stimulation database. Mean follow-up was 3.7 years; the number of patients with follow-up data ranged from 60 to 93, depending on the outcome. The primary outcome was change in attack frequency. At last follow-up, 69% (64/93) of patients had a reduction of $\geq 50\%$ in attack frequency, and 73% (68/93) reported at least a 30% reduction in frequency. Overall response rate was 77% (72/93); including 59% of patients who reported excellent response to treatment and 18% who reported mild response; 23% were nonresponders. Statistically significant improvements from baseline were also reported for quality of life measures. Adverse events were common, occurring in 64% (67/105) of patients, including need for reoperation in 28% (29/105).

Leone et al (2017) published a case series on use of occipital nerve stimulation in 35 patients with chronic cluster headache. 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 number of headaches per day and were considered responders. In 12 (40%) patients, improvement was considered stable (ie, ≤ 3 headache attacks per month).

Limitations of the series reporting on cluster headaches included lack of blinding and comparison groups

Hemicrania Continua

The evidence evaluating the use of occipital nerve stimulation for hemicrania continua consists of a small crossover study. Burns et al (2008) reported on the efficacy of continuous unilateral occipital nerve stimulation in 6 patients. Pain on a 10-point scale was recorded hourly in patient 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), one reported 30% less pain, and one reported 20% worse pain. Adverse events were mild and associated with transient overstimulation.

Headache Associated with Chiari Malformation

Vadivelu et al (2012) reported on a 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 of 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

A systematic review by Sweet et al (2015) 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 on occipital neuralgia due to the lack of RCTs or other controlled studies.

Section Summary: Non-Migraine Headaches

The evidence on occipital nerve stimulation for treatment of non-migraine headaches primarily consists of case series. 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 that a substantial number of patients improved after occipital nerve stimulation, the studies lacked blinding and comparison groups. One electrical dose-controlled RCT failed to demonstrate a significant difference in reduction of mean attack frequencies when subjects with medically intractable chronic cluster headache were treated at 100% versus 30% (sham) stimulation.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Pain and Neuroscience

In 2022, the American Society of Pain and Neuroscience released evidence-based clinical guidelines addressing the use of implantable peripheral nerve stimulation in the treatment of chronic pain, including chronic migraine. The guidelines conclude that "Stimulation of occipital nerves may be offered to patients with chronic migraine headache when conservative treatments have failed. The average effect size for relief of migraine symptoms is modest to moderate (Level I, Grade B). There is presently insufficient evidence to recommend stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain (Level II-3, Grade C)."

Congress of Neurological Surgeons

In 2015, the Congress of Neurological Surgeons released an evidence-based guideline that stated, "the use of occipital nerve stimulators 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 literature (see Rationale section) that only identified case series. An update of the review was published in 2023. The update included a systematic review of the relevant literature, but the new studies did not result in modification of the prior recommendations.

Department of Veterans Affairs and Department of Defense

The Department of Veterans Affairs (VA) and the Department of Defense (DoD) released a Clinical Practice Guideline for Management of Headache in 2023. The guideline recommendations were based on a systematic review and included strength of recommendation ratings. The guidelines stated that “There is insufficient evidence to recommend for or against any form of neuromodulation for the treatment and/or prevention of migraine’ including external combined occipital and trigeminal neurostimulation systems.”

National Institute for Health and Care Excellence

In 2013, the National Institute for Health and Care Excellence issued a guidance informed by a systematic review noting that the evidence on occipital nerve stimulation for intractable chronic migraine showed “some efficacy in the short term but very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery.”

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

REFERENCES

1. Chen YF, Bramley G, Unwin G, et al. Occipital nerve stimulation for chronic migraine--a systematic review and meta-analysis. *PLoS One*. 2015; 10(3): e0116786. PMID 25793740
2. Yang Y, Song M, Fan Y, et al. Occipital Nerve Stimulation for Migraine: A Systematic Review. *Pain Pract*. Apr 2016; 16(4): 509-17. PMID 25865962
3. Saper JR, Dodick DW, Silberstein SD, et al. Occipital nerve stimulation for the treatment of intractable chronic migraine headache: ONSTIM feasibility study. *Cephalalgia*. Feb 2011; 31(3): 271-85. PMID 20861241
4. Silberstein SD, Dodick DW, Saper J, et al. Safety and efficacy of peripheral nerve stimulation of the occipital nerves for the management of chronic migraine: results from a randomized, multicenter, double-blinded, controlled study. *Cephalalgia*. Dec 2012; 32(16): 1165-79. PMID 23034698
5. Dodick DW, Silberstein SD, Reed KL, et al. Safety and efficacy of peripheral nerve stimulation of the occipital nerves for the management of chronic migraine: long-term results from a randomized, multicenter, double-blinded, controlled study. *Cephalalgia*. Apr 2015; 35(4): 344-58. PMID 25078718
6. Burns B, Watkins L, Goadsby PJ. Treatment of hemicrania continua by occipital nerve stimulation with a bion device: long-term follow-up of a crossover study. *Lancet Neurol*. Nov 2008; 7(11): 1001-12. PMID 18845482
7. Burns B, Watkins L, Goadsby PJ. Treatment of intractable chronic cluster headache by occipital nerve stimulation in 14 patients. *Neurology*. Jan 27 2009; 72(4): 341-5. PMID 19171831

8. Magis D, Gerardy PY, Remacle JM, et al. Sustained effectiveness of occipital nerve stimulation in drug-resistant chronic cluster headache. *Headache*. Sep 2011; 51(8): 1191-201. PMID 21848953
9. Mueller OM, Gaul C, Katsarava Z, et al. Occipital nerve stimulation for the treatment of chronic cluster headache - lessons learned from 18 months experience. *Cent Eur Neurosurg*. May 2011; 72(2): 84-9. PMID 21448856
10. Fontaine D, Blond S, Lucas C, et al. Occipital nerve stimulation improves the quality of life in medically-intractable chronic cluster headache: Results of an observational prospective study. *Cephalalgia*. Oct 2017; 37(12): 1173-1179. PMID 27697849
11. Leone M, Proietti Cecchini A, Messina G, et al. Long-term occipital nerve stimulation for drug-resistant chronic cluster headache. *Cephalalgia*. Jul 2017; 37(8): 756-763. PMID 27250232
12. Miller S, Watkins L, Matharu M. Treatment of intractable chronic cluster headache by occipital nerve stimulation: a cohort of 51 patients. *Eur J Neurol*. Feb 2017; 24(2): 381-390. PMID 27995704
13. Leplus A, Fontaine D, Donnet A, et al. Long-Term Efficacy of Occipital Nerve Stimulation for Medically Intractable Cluster Headache. *Neurosurgery*. Jan 13 2021; 88(2): 375-383. PMID 32985662
14. Vadivelu S, Bolognese P, Milhorat TH, et al. Occipital nerve stimulation for refractory headache in the Chiari malformation population. *Neurosurgery*. Jun 2012; 70(6): 1430-6; discussion 1436-7. PMID 22418582
15. Sweet JA, Mitchell LS, Narouze S, et al. Occipital Nerve Stimulation for the Treatment of Patients With Medically Refractory Occipital Neuralgia: Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline. *Neurosurgery*. Sep 2015; 77(3): 332-41. PMID 26125672
16. National Institute for Health and Care Excellence. Occipital nerve stimulation for intractable chronic migraine [IPG452]. 2013; <https://www.nice.org.uk/guidance/ipg452> . Accessed March 7, 2023.
17. Membrilla JA, Roa J, Díaz-de-Terán J. Preventive treatment of refractory chronic cluster headache: systematic review and meta-analysis. *J Neurol*. 2023 Feb;270(2):689-710. doi: 10.1007/s00415-022-11436-w. Epub 2022 Oct 31. PMID: 36310189
18. VA/DoD Clinical Practice Guideline. (2023). Management of Headache Work Group. Washington, DC:U.S. Government Printing Office. <https://www.healthquality.va.gov/guidelines/pain/headache/VA-DoD-CPG-Headache-Full-CPG.pdf>
19. Staudt MD, Hayek SM, Rosenow JM, et al. Congress of Neurological Surgeons Systematic Review and Evidence-Based Guidelines for Occipital Nerve Stimulation for the Treatment of Patients With Medically Refractory Occipital Neuralgia: Update. *Neurosurgery*. Sep 01 2023; 93(3): 493-495. PMID 37458729
20. Wilbrink LA, de Coo IF, Doesborg PGG, et al. Safety and efficacy of occipital nerve stimulation for attack prevention in medically intractable chronic cluster headache (ICON): a randomised, double-blind, multicentre, phase 3, electrical dose-controlled trial. *Lancet Neurol*. Jul 2021; 20(7): 515-525. PMID 34146510
21. Brandt RB, Wilbrink LA, de Coo IF, et al. A prospective open label 2-8 year extension of the randomised controlled ICON trial on the long-term efficacy and safety of occipital nerve stimulation in medically intractable chronic cluster headache. *EBioMedicine*. Dec 2023; 98: 104895. PMID 38007947
22. Strand N, D'Souza RS, Hagedorn JM, et al. Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve

Stimulation in the Treatment of Chronic Pain. J Pain Res. 2022; 15: 2483-2504. PMID 36039168

23. Hayes, Inc. Health Technology Assessment. Occipital Nerve Stimulation for Chronic Migraine Headache. Annual review: June 13, 2022. Available at: www.hayesinc.com. Accessed May 2025.
24. Hayes, Inc. Health Technology Assessment. Occipital Nerve Stimulation for Chronic Cluster Headache. Annual review: August 29, 2023. Available at: www.hayesinc.com. Accessed May 2025.
25. Hayes, In. Health Technology Assessment. Electrical Stimulation of the Occipital Nerve for Treatment of Occipital Neuralgia. Annual review: January 6, 2014. Available at: www.hayesinc.com. Accessed May 2025.
26. UpToDate. Garza I., Schwedt TJ, Robertson CE., et al. Chronic Migraine. Topic last updated October 3, 2024. Literature review current through April 2025. Available at: <http://www.uptodate.com>. Accessed May 2025.
27. UpToDate. May A., Swanson JW., Goddeau Jr RP., Cluster Headache: Treatment and Prognosis. Topic last updated May 13, 2025. Literature review current through April 2025. Available at: <http://www.uptodate.com>. Accessed May 2025.
28. UpToDate. Garza I., Schwedt TJ., Swanson JW., et al. Hemicrania Continua. Topic last updated October 9, 2024. Literature review current through April 2025. Available at: <http://www.uptodate.com>. Accessed May 2025.
29. UpToDate. Garza I., Robertson CE., Goddeau Jr RP. Occipital Neuralgia. Topic last updated March 3, 2025. Literature review current through April 2025. Available at: <http://www.uptodate.com>. Accessed May 2025.

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis 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 electrodes; peripheral nerve (excludes sacral nerve)
	64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)

	64568	Incision for 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
	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
	64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
	64999	Unlisted procedure, nervous system
HCPCS		
	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
	C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
	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
Type of Service	Surgery	
Place of Service	Outpatient/Inpatient	

POLICY HISTORY

Date	Action	Action
June 2025	Annual Review	Policy Renewed
June 2024	Annual Review	Policy Renewed
June 2023	Annual Review	Policy Revised
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

Date	Action	Action
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

*CPT® is a registered trademark of the American Medical Association.