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Occipital Nerve Stimulation

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Occipital nerve stimulation **is considered experimental, investigational and/or unproven** for all indications.

Policy Guidelines

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

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.

Headache

There are 4 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 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

Medical policies 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 policy.

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 individuals 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.

Systematic Reviews

Chen et al. (2015) identified 5 RCTs and 7 case series with at least 10 patients. (1) 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) (2) 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. (3) 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 ≥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. (4) 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. (5) 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., ≥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 medical policy 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 policy.

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 individuals 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.

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. (6) 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. (7) 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 ≥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.

<u>Case Series</u>

Numerous case series assessing cluster headache were identified, with sample sizes ranging from 10 to 105 patients. (8-13) The largest of these case series included 105 patients with

refractory cluster headache in a French occipital nerve stimulation database. (14) 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 ≥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. (12) 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 (i.e., ≤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. (15) 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. (16) 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. (17) 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.

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.

Practice Guidelines and Position Statements

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. (18) 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.” (17) 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. (19) The update included a new 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. (20) 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.” (21)

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT01842763	French Database of Occipital Nerves Stimulation in the Treatment of Refractory Chronic Headache Disorders	246	Sep 2027
NCT06450444[a]	Randomized, Double-blind, Sham-controlled Trial to Investigate Combined Occipital and Supra-orbital Neuromodulation in Resistant Migraine (RECLAIM)	62	Feb 2027

NCT02725554[a]	Prospective, Randomized, Controlled, Multi-Center Study of Wireless Nerve Stimulation in the Treatment of Chronic Migraine	144	Dec 2026
NCT04937010	Efficacy and Safety of Occipital Nerve Stimulation in Trigeminal Autonomic Cephalalgias: A Double-blind, Phase II, Randomized, Controlled Trial	20	Sep 2026
NCT05804396[a]	The SP-303 PERL Study - Combined Occipital and Trigeminal Nerve Stimulation (eCOT-NS) for Preventive Treatment of Migraine	0 (withdrawn)	Nov 2024
NCT05023460	Treatment of Chronic Cluster Headache (Horton's Headache) With Transcutaneous Electrical Nerve Stimulation and Occipital Nerve Stimulation	5 (estimated)	Apr 2026
NCT03475797	Evaluation of Occipital Nerve Stimulation in Intractable Occipital Neuralgia: A Multicentric, Controlled, Randomized Study	22 (actual)	Sep 2021

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	61885, 61886, 64553, 64568, 64569, 64570, 64575, 64999
HCPCS Codes	C1767, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2025	Document updated. Coverage unchanged. No new references added.
09/15/2024	Document updated with literature review. Coverage unchanged. References 16 and 17 added.
01/01/2024	Reviewed. No changes.
09/15/2022	Document updated with literature review. Coverage unchanged. Reference 13 added.
08/01/2021	Reviewed. No changes.

01/01/2021	Document updated with literature review. Coverage unchanged. No new references added.
08/01/2019	Reviewed. No changes.
07/15/2018	Document updated with literature review. Coverage unchanged. References 10-12 added.
07/15/2017	Reviewed. No changes.
10/01/2016	Document updated with literature review. Coverage unchanged.
05/15/2015	Reviewed. No changes.
08/15/2014	Document updated with literature review. Coverage unchanged
06/01/2011	CPT/HCPCS code(s) updated
12/01/2010	New medical document. Occipital nerve stimulation is considered experimental, investigational and unproven for all indications