Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Occipital Nerve Stimulation

Description/Background

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 four types of headache: vascular, muscle contraction (tension), 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 6–15% in adult men and from 14%–35% in adult women. Migraine headaches may last a day or more and can strike as often as several times a week or as rarely as once every few years.

Treatment of Migraine

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 amitriptyline, propranolol and other β-blockers, topiramate and other antiepileptic drugs, and verapamil.

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 (NSAIDs), 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 one headache every other day up 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 by person, 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 in 1,000.

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 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.

Medical Policy Statement

Occipital nerve stimulation is experimental/investigational for all indications. It has not been scientifically demonstrated to improve patient clinical outcomes over conventional treatment.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

64999

Rationale

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 is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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.

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 randomized controlled trials (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.

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 question addressed in this evidence review is: Does occipital nerve stimulation improve the net health outcome in individuals who have migraines?

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

Populations

The relevant population of interest are individuals with migraine headache.

Intervention

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), which are prescribed by general practitioner physicians or neurologists in an outpatient clinical setting.

Outcomes

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

Review of Evidence

Systematic Reviews

Two systematic reviews of the literature on occipital nerve stimulation have been published, both including RTCs and observational studies. 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 two were single-center crossover trials. All five included a sham control group and one trial included a medication management group. Risk of bias was judged to be high or unclear for all trials. Meta-analysis were performed on two outcomes. A pooled analysis of two studies did not find a significant difference in response rate 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 three 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=.003).

Yang et al (2016) [2] identified the same five RCTs as Chen in their systematic review. The Yang review only included studies conducted with patients who had migraines for 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 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%. Reviewers noted that the case series were subject to biases (e.g., inability to control for 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 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 minute per day, 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 three (6%) of the 51 subjects were hospitalized for adverse events (infection, lead migration and 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 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 intention to treat (ITT) population and for the 125 patients who met selection criteria for intractable chronic migraine. Twenty-four patients were excluded from analysis due to explanation of the occipital nerve stimulation system (n=18) or loss to follow-up. Mean headache days at baseline were 21.6 for the intention to treat (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 one 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 to sham stimulation, response rates (i.e., ≥50% reduction in VAS 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 Test 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 question addressed in this evidence review is: Does occipital nerve stimulation improve the net health outcome in individuals who have non-migraine headache?

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

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

Intervention
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), which are prescribed by general practitioner physicians or neurologists in an outpatient clinical setting.

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

Review of Evidence

Case Series

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.[6] 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 six 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.

Cluster Headache
Numerous case series assessing cluster headache were identified, with sample sizes ranging from 10 to 105 patients.[7,8,9,10,11,12] The largest of these case series included 105 patients with refractory cluster headache in a French occipital nerve stimulation database.[13,] 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.[11] 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.

Headache Associated with Chiari Malformation
Vadivelu et al (2012) reported on a series of 22 patients with Chiari malformation and persistent occipital headaches.[14] 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 nine small case series (<15 patients each) assessing the efficacy of occipital nerve stimulation for treating medically refractory occipital neuralgia.[15] Reviewers did not pool study findings. Conclusions cannot be drawn on the impact of occipital nerve stimulation on occipital neuralgia due to lack of RCTs or other controlled studies.

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

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, systematic reviews of RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Systematic reviews identified five 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 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). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

Congress of Neurological Surgeons

In 2015,the Congress of Neurological Surgeons released an evidenced-based guideline that stated: "the use of occipital nerve stimulation is a treatment option for patients with medically refractory occipital neuralgia."[15.] 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.[16] 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.[17] 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 (NICE)

In 2013, the National Institute for Health and Care Excellence issued a guidance informed by a systematic review that the evidence on occipital nerve stimulation for intractable chronic migraine showed "some efficacy in the short term but there is very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery.[18]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05023460	Treatment of Chronic Cluster Headache (Horton's Headache) With Transcutaneous Electrical Nerve Stimulation and Occipital Nerve Stimulation	40	Jul 2024
NCT05804396	The SP-303 PERL Study - Combined Occipital and Trigeminal Nerve Stimulation (eCOT-NS) for Preventive Treatment of Migraine	57	Aug 2024
NCT01842763	French Database of Occipital Nerves Stimulation in the Treatment of Refractory Chronic Headache Disorders	50	July 2026
NCT04937010	Efficacy and Safety of Occipital Nerve Stimulation in Trigeminal Autonomic Cephalalgias: A Double-blind, Phase II, Randomized, Controlled Trial	20	Sep 2026
Unpublished			
NCT03475797	Evaluation of Occipital Nerve Stimulation in Intractable Occipital Neuralgia:A Multicentric, Controlled, Randomized Study	22 (actual)	September 2021

NCT: national clinical trial.

Government Regulations
National / Local:

National Coverage Determination for Electrical Nerve Stimulators (160.7)
Effective Date of this version: 8/7/1995

Benefit Category
Prosthetic Devices

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Indications and Limitations of Coverage
Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A. Implanted Peripheral Nerve Stimulators
Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than 1/2 inch.

Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

NOTE: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in §160.7.1, such use of the stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

B. Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators)
The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

1. Types of Implantations
There are two types of implantations covered by this instruction:
•Dorsal Column (Spinal Cord) Neurostimulation - The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered.
•Depth Brain Neurostimulation - The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

2. Conditions for Coverage
No payment may be made for the implantation of dorsal column or depth brain stimulators or services and supplies related to such implantation, unless all of the conditions listed below have been met:
•The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;
•With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;
•Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);
•All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient (including that required to satisfy item c) must be available; and
•Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Medicare Administrative Contractors may find it helpful to work with Quality Improvement Organizations to obtain the information needed to apply these conditions to claims.

There is no Local Coverage Determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation
- Interferential Stimulation (Sympathetic Therapy)
- Microcurrent Electrical Neurostimulation (MENS)

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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 11 2015. PMID 25865962
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6. Burns B, Watkins L, Goadsby PJ. Treatment of Hemicranias continua by occipital nerve stimulation with a bion device: long-term follow-up of a crossover study. Lancet Neurol. Nov 2008;7(11):1001-1012. 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):341-345. 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):1191-1201. 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. Cen Eur Neurosurg. May 2011;72(2):84-89. PMID 21448856
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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
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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):1430-1436; discussion 1436-1437. 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):332-341. PMID 26125672
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17. 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. Accessed May 31, 2024.
18. National Institute for Health and Care Excellence. Occipital nerve stimulation for intractable chronic migraine [IPG452]. 2013; https://www.nice.org.uk/guidance/ipg452. Accessed May 31, 2024.
19. Blue Cross Blue Shield Association. Occipital Nerve Stimulation. Medical Policy Reference Manual. Policy #7.01.125, original policy date 2/11/10, last review date May 2024.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through May 31, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/12	10/11/11	11/9/11	Joint policy established
3/1/13	12/11/12	12/31/12	Routine review of non-covered service. References updated.
3/1/14	12/10/13	1/6/14	Routine review of non-covered service. References updated. No change in policy status.
3/1/15	12/12/14	12/29/14	Routine review of non-covered service. References updated. No change in policy status.
3/1/16	12/10/15	12/10/15	Routine policy maintenance. No change in policy status.
3/1/17	12/13/16	12/13/16	Removed references for Blue Cross Complete. Routine policy maintenance. No change in status.
3/1/18	12/12/17	12/12/17	Routine policy maintenance. Added reference 10 and 11. No change in policy status.
1/1/19	10/16/18	10/16/18	Routine policy maintenance. No change in policy status.
1/1/20	10/15/19		Routine maintenance.
1/1/21	10/20/20		Routine maintenance.
11/1/21	8/17/21		Routine maintenance. No change in policy status.
11/1/22	8/16/22		Routine maintenance. No change in policy position.
11/1/23	8/15/23		Routine maintenance. No change in policy position. Vendor: N/A (ky)
11/1/24	8/20/24		Routine maintenance. No change in policy position. Vendor: N/A (ky)

Next Review Date: 3rd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: OCCIPITAL NERVE STIMULATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See Government Regulations Section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A