

Occipital Nerve Stimulation

Policy # 00253

Original Effective Date: 03/19/2010

Current Effective Date: 07/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) is addressed separately in medical policy 00144.

Note: Spinal Cord and Dorsal Root Ganglion Stimulators is addressed separately in medical policy 00260.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers occipital nerve stimulation (ONS) for all indications to be **investigational**.*

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 medical policy addresses potential off-label use.

Background/Overview

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.

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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, and 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.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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^{TM‡} 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^{TM‡} Neuromodulation System (St. Jude Medical) was approved by the FDA for spinal cord stimulation, and the Eon^{TM‡} stimulator has received CE mark approval in Europe for the treatment of chronic migraines. In 2017, the AnkerStim^{TM‡} lead received CE mark approval for intractable chronic cluster headache.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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 (eg, 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

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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 (eg, 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.

Supplemental Information

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 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. The guideline recommendations were based on a systematic review and included strength of recommendation ratings. The guidelines stated

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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.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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
<i>Ongoing</i>			
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

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<i>Unpublished</i>			
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 (HortONS)	5 (estimated)	Apr 2026
NCT03475797	Evaluation of Occipital Nerve Stimulation in Intractable Occipital Neuralgia: A Multicentric, Controlled, Randomized Study (StimO)	22 (actual)	Sept 2021

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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03/05/2010	Medical Policy Committee approval
03/19/2010	Medical Policy Implementation Committee approval. New Policy.
12/31/2010	Coding updated
02/03/2011	Medical Policy Committee approval
02/16/2011	Medical Policy Implementation Committee approval. No change to coverage.
02/02/2012	Medical Policy Committee approval
02/15/2012	Medical Policy Implementation Committee approval. No change to coverage.
02/07/2013	Medical Policy Committee approval
02/20/2013	Medical Policy Implementation Committee approval. No change to coverage.
02/06/2014	Medical Policy Committee approval
02/19/2014	Medical Policy Implementation Committee approval. No change to coverage.
03/05/2015	Medical Policy Committee approval
03/20/2015	Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
06/02/2016	Medical Policy Committee approval
06/20/2016	Medical Policy Implementation Committee approval. No change to coverage.
09/08/2016	Coding update
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee approval
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/10/2019	Coding update
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/14/2020	Coding update
06/03/2021	Medical Policy Committee review

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06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2021	Coding update
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/05/2025	Medical Policy Committee review
06/11/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	61885, 61886, 64553, 64555, 64568, 64569, 64570, 64575, 64999 Delete codes effective 07/01/2025: 61888, 63650
HCPCS	L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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