



# Louisiana

## Occipital Nerve Stimulation

Policy # 00253

Original Effective Date: 03/19/2010

Current Effective Date: 07/08/2024

*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 Stimulation 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**.\*

## 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  $\beta$ -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, 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 woman. 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

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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.

## **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<sup>TM†</sup> 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<sup>TM†</sup> Neuromodulation System (St. Jude Medical) was approved by the FDA for spinal cord stimulation, and the Eon<sup>TM†</sup> stimulator has received CE mark approval in Europe for the treatment of chronic migraines.

## **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 federal 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.

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### **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 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 (eg, 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**

### **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 evidence-based guideline that stated, "the use of occipital nerve stimulators is a treatment option for patients with medically refractory

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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 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 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.

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**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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	240	Jul 2026
NCT04937010	Efficacy and Safety of Occipital Nerve Stimulation in Trigeminal Autonomic Cephalalgias: A Double-blind, Phase II, Randomized, Controlled Trial	20	Sep 2026
<i>Unpublished</i>			
NCT03475797	Evaluation of Occipital Nerve Stimulation in Intractable Occipital Neuralgia: A Multicentric, Controlled, Randomized Study	22 (actual)	Sept 2021

NCT: national clinical trial.

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## **Policy History**

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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  |

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- 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
- 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.

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Next Scheduled Review Date: 06/2025

## **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 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, 61888, 63650, 64553, 64555, 64568, 64569, 64570, 64575, 64999
HCPCS	L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689
ICD-10 Diagnosis	All related Diagnoses

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\*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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