Occipital Nerve Stimulation

Policy # 00253
Original Effective Date: 03/19/2010
Current Effective Date: 07/12/2021

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.
Treatment

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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.

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

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 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 Food and Drug Administration 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 Food and Drug Administration for spinal cord stimulation and the Eon™‡ stimulator has received CE mark approval in Europe for the treatment of chronic migraines.

Rationale/Source

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 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.

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."

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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
Ongoing			
NCT01842763	French Database of Occipital Nerves Stimulation in the Treatment of Refractory Chronic Headache Disorders	50	December 2023
NCT03475797	Evaluation of Occipital Nerve Stimulation in Intractable Occipital Neuralgia: A Multicentric, Controlled, Randomized Study	70	December 2022
Unpublished			
NCT01151631	Occipital Nerve Stimulation in Medically Intractable Chronic Cluster Headache (ICON).	144	March 2019
NCT03398668	Combined Occipital and Supraorbital Transcutaneous Nerve Stimulation for Treatment of Migraine	58	December 2018

NCT: national clinical trial.

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References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Occipital Nerve Stimulation", 7.01.125, May 2021.
2. 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
3. Yang Y, Song M, Fan Y, et al. Occipital Nerve Stimulation for Migraine: A Systematic Review. Pain Pract. Apr 2016; 16(4): 509-17. PMID 25865962
4. Saper JR, Dodick DW, Silberstein SD, et al. Occipital nerve stimulation for the treatment of intractable chronic migraine headache: ONSTIM feasibility study. Cephalalgia. Feb 2011; 31(3): 271-85. PMID 20861241
5. Silberstein SD, Dodick DW, Saper J, et al. Safety and efficacy of peripheral nerve stimulation of the occipital nerves for the management of chronic migraine: results from a randomized, multicenter, double-blinded, controlled study. Cephalalgia. Dec 2012; 32(16): 1165-79. PMID 23034698
6. Dodick DW, Silberstein SD, Reed KL, et al. Safety and efficacy of peripheral nerve stimulation of the occipital nerves for the management of chronic migraine: long-term results from a randomized, multicenter, double-blinded, controlled study. Cephalalgia. Apr 2015; 35(4): 344-58. PMID 25078718
7. Burns B, Watkins L, Goadsby PJ. Treatment of hemicrania continua by occipital nerve stimulation with a bion device: long-term follow-up of a crossover study. Lancet Neurol. Nov 2008; 7(11): 1001-12. PMID 18845482
8. Burns B, Watkins L, Goadsby PJ. Treatment of intractable chronic cluster headache by occipital nerve stimulation in 14 patients. Neurology. Jan 27 2009; 72(4): 341-5. PMID 19171831
9. Magis D, Gerardy PY, Remacle JM, et al. Sustained effectiveness of occipital nerve stimulation in drug-resistant chronic cluster headache. Headache. Sep 2011; 51(8): 1191-201. PMID 21848953
10. Mueller OM, Gaul C, Katsarava Z, et al. Occipital nerve stimulation for the treatment of chronic cluster headache - lessons learned from 18 months experience. Cent Eur Neurosurg. May 2011; 72(2): 84-9. PMID 21448856
11. Fontaine D, Blond S, Lucas C, et al. Occipital nerve stimulation improves the quality of life in medically-intractable chronic cluster headache: Results of an observational prospective study. Cephalalgia. Oct 2017; 37(12): 1173-1179. PMID 27697849

12. Leone M, Proietti Cecchini A, Messina G, et al. Long-term occipital nerve stimulation for drug-resistant chronic cluster headache. Cephalalgia. Jul 2017; 37(8): 756-763. PMID 27250232
13. 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
14. Leplus A, Fontaine D, Donnet A, et al. Long-Term Efficacy of Occipital Nerve Stimulation for Medically Intractable Cluster Headache. Neurosurgery. Jan 13 2021; 88(2): 375-383. PMID 32985662
15. Vadivelu S, Bolognese P, Milhorat TH, et al. Occipital nerve stimulation for refractory headache in the Chiari malformation population. Neurosurgery. Jun 2012; 70(6): 1430-6; discussion 1436-7. PMID 22418582
16. Sweet JA, Mitchell LS, Narouze S, et al. Occipital Nerve Stimulation for the Treatment of Patients With Medically Refractory Occipital Neuralgia: Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline. Neurosurgery. Sep 2015; 77(3): 332-41. PMID 26125672
17. National Institute for Health and Care Excellence. Occipital nerve stimulation for intractable chronic migraine [IPG452]. 2013; https://www.nice.org.uk/guidance/ipg452.

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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
06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2021	Coding update

Next Scheduled Review Date: 06/2022

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 2020 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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CPT is a registered trademark of the American Medical Association.

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	G43.001-G43.D1, G44.001-G44.89, I70.238, I70.248, M53.81-M53.83, M54.81, R51.0-R51.9 Codes added eff 10/1/2021: M54.50-M54.59

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.