Occipital Nerve Stimulation

Medicare Advantage Medical Policy # MA-222
Original Effective Date: 08/01/2026
Current Effective Date: 08/01/2026

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

Note: Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) is addressed separately in medical policy MA-139.

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.

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, andverapamil, 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.

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™‡ IPG device (Medtronic), an implantable pulse generator, was approved by the FDA through the premarket approval process for management of chronic, intractable pain of the trunk or limbs, and off-label use for headache is described in the literature. The Genesis™‡ Neuromodulation System (St. Jude Medical) was approved by the FDA for spinal cord stimulation, and the Eon™‡ stimulator has received CE mark approval in Europe for the treatment of chronic migraines. In 2017, the AnkerStim™™‡ lead received CE mark approval for intractable chronic cluster headache.

Rationale/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.

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 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 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
Ongoing			
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
Unpublished			
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.

References

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 2016; 16(4): 509-17. PMID 25865962
3. 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
4. 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
5. 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
6. Wilbrink LA, de Coo IF, Doesborg PGG, et al. Safety and efficacy of occipital nerve stimulation for attack prevention in medically intractable chronic cluster headache (ICON): a randomised, double-blind, multicentre, phase 3, electrical dose-controlled trial. Lancet Neurol. Jul 2021; 20(7): 515-525. PMID 34146510
7. Brandt RB, Wilbrink LA, de Coo IF, et al. A prospective open label 2-8 year extension of the randomised controlled ICON trial on the long-term efficacy and safety of occipital nerve stimulation in medically intractable chronic cluster headache. EBioMedicine. Dec 2023; 98: 104895. PMID 38007947
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. 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
16. 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
17. 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
18. Strand N, D'Souza RS, Hagedorn JM, et al. Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain. J Pain Res. 2022; 15: 2483-2504. PMID 36039168
19. Staudt MD, Hayek SM, Rosenow JM, et al. Congress of Neurological Surgeons Systematic Review and Evidence-Based Guidelines for Occipital Nerve Stimulation for the Treatment of Patients With Medically Refractory Occipital Neuralgia: Update. Neurosurgery. Sep 01 2023; 93(3): 493-495. PMID 37458729
20. 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.
21. National Institute for Health and Care Excellence. Occipital nerve stimulation for intractable chronic migraine [IPG452]. 2013; https://www.nice.org.uk/guidance/ipg452.

Policy History

Original Effective Date: 08/01/2026
Current Effective Date: 08/01/2026
05/19/2026 Utilization Management Committee review/approval. New policy.

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 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.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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
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.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's 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 Health Plan 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.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.