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MEDICAL POLICY – 7.01.125

Occipital Nerve Stimulation

BCBSA Ref. Policy:	7.01.125	
Effective Date:	July 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	June 10, 2024	1.01.507 Electrical Stimulation Devices
Replaces:	N/A	7.01.588 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
		7.01.555 Facet Joint Denervation
		7.01.546 Spinal Cord and Dorsal Root Ganglion Stimulation

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POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

The occipital nerves run through the muscles on the back of the head and over the scalp. Irritation to these nerves can create shooting or tingling pain, usually on one side of the head or near one eye. The scalp can also be very painful to the touch. Occipital nerve stimulation is a being studied as a technique for migraines and other headaches that don't respond to medication. Occipital nerve stimulation aims to treat pain with electrical signals. Wires are implanted at the base of the skull. The wires are connected to a small power source surgically placed below the skin, usually in the upper chest. The power source generates the electricity, which then sends the signal through the wires to stimulate the occipital nerve. It's thought that the electrical signals block or scramble the pain signals from the nerves. Because more studies are needed to see if this technique is effective, occipital nerve stimulation is considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Occipital nerve stimulation	**Occipital nerve stimulation is considered investigational for all indications.**

Coding

Code	Description
CPT	
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve
64568	Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
HCPCS	
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension

Code	Description
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

Occipital nerve stimulation (ONS) delivers a small electrical charge to the occipital nerve intended to prevent migraines and other headaches in individuals 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.

Background

Headache

There are four 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 three 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 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 pain with 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 individuals.

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 (drooping eyelid), 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 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 individuals 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 individual 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.

Summary of Evidence

For individuals who have migraine headaches refractory to preventive medical management who receive ONS, 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 to placebo, response rates to ONS did not differ significantly but did reduce the number of days with prolonged moderate-to-severe headache. ONS 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 ONS, 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 individuals were available only for treatment of cluster headache. Although the case series tended to find that a substantial number of individuals improved after ONS, these studies lacked blinding and comparison groups. RCTs are needed to compare outcomes between ONS 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and 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	240	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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT03475797	Evaluation of Occipital Nerve Stimulation in Intractable Occipital Neuralgia: A Multicentric, Controlled, Randomized Study	22 (actual)	Sept 2021

NCT: national clinical trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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."[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

In 2013, the National Institute for Health and Care Excellence issued a guidance informed by a systematic review noting that the evidence on ONS 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."[18]

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The US Food and Drug Administration (FDA) has not cleared or approved any ONS device for treatment of headache. In 1999, the Synergy IPG (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.

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History

Date	Comments
04/13/10	Add to Surgery Section - New Policy
05/10/11	Replace Policy - Policy updated with literature search, reference 6 updated, reference 7 added; policy statement unchanged. CPT coding updated in Policy Guidelines. ICD-10 codes added to policy.
01/06/12	Replace Policy – Policy updated with literature search through August 2011; references 7 and 8 added and references reordered; policy statement unchanged.
04/17/12	Related Policies updated: 7.01.546 added to replace 7.01.25 which has been deleted.
09/26/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
10/17/12	Update Related Policies – Add 7.01.135.
01/29/13	Replace policy. Policy updated with literature search through August 2012; references 2 and 10 added and references reordered; policy statement unchanged.
10/16/13	Update Related Policies. Change title to policy 7.01.135.
01/21/14	Replace policy. Policy updated with literature review through September 27, 2013. References 2, 13 added; others renumbered/removed. Policy statement unchanged. ICD-10-PCS codes removed; this is an outpatient procedure and they would not apply.
05/23/14	Update Related Policy. Add 7.01.555.
10/22/14	Update Related Policies. Remove 7.01.135 as it was archived.
01/28/15	Annual Review. Policy updated with literature review through October 7, 2014; reference 3 added; some references removed; policy statement unchanged.
01/29/16	Minor update. Added HCPCS code L8679.
07/01/16	Annual Review, approved June 14, 2016. Updated with literature review. References 1-2, and 11 added. Policy statement unchanged.
07/01/17	Annual Review, approved June 6 2017. Policy moved into new format, Policy updated with literature review through February 23, 2017; references 10-12 added. Removed CPT code 64999. Policy statement unchanged.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; no references added. Policy statement unchanged.

Date	Comments
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; no references added. Policy statement unchanged. Removed CPT code 64570 and HCPCS code L8684.
07/01/20	Annual Review, approved June 4, 2020. Policy updated with literature review through February 2020; no references added. Policy statements unchanged.
07/02/2020	Coding update. Removed HCPCS L8679.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through March 10, 2021; reference added. Policy statements unchanged. Added HCPC codes C1767 and C1778.
01/01/22	Coding update, updated description for CPT code 64568.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through January 17, 2022; no references added. Policy statements unchanged.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through January 16, 2023; no references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
10/04/23	Updated related policy. Policy 7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy was renumbered to 7.01.588 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through February 23, 2024; references added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.