Clinical Policy: Occipital Nerve Stimulation for Headache

Reference Number: HNCA.CP.MP.432

Coding Implications
Revision Log

Last Review Date: 11/19

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Medical necessity criteria for the review of occipital nerve stimulation (ONS), also called peripheral nerve stimulation (PFS), a form of neuromodulation therapy aimed at treating headache and craniofacial pain.

Occipital nerve stimulation is a form of neuromodulation that is reversible and adjustable and can be tailored to an individual's specific needs. 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

Policy/Criteria

I. It is the policy of Health Net of California that ONS may be considered **medically necessary** only for carefully selected individuals with intractable occipital neuralgia that is refractory to standard treatment, and is having a negative impact on quality of life.

II. It is the policy of Health Net of California that ONS is **investigational** for any other circumstances than those specified above.

Background

During ONS, a neurostimulator is implanted under the skin at the base of the head. The lead is placed into the subcutaneous tissues innervated by the greater and lesser occipital nerves, and the pulse generator is implanted into a subcutaneous pocket in the chest, abdomen, or back.

Indications for ONS include chronic, intractable primary or secondary headache disorders and neuropathic pain involving the occipital or suboccipital region. Occipital neuralgia is a form of headache that involves the posterior scalp, in the greater or lesser occipital nerve distribution, with pain that can be severe and debilitating. [4, 7]

Neurostimulation is FDA-approved for the treatment of certain intractable pain syndromes, although it is not approved for headache and craniofacial pain and thus occipital nerve stimulation represents an off-label use. [4]

National Institute for Health and Care Excellence (NICE)

Evidence on occipital nerve stimulation (ONS) for intractable chronic migraine shows some efficacy in the short term but very little evidence about long-term outcomes. [6]

American Association of Neurological Surgeons (AANS) & Congress of Neurological Surgeons Joint Guideline Committees
Based on data derived from this systematic literature review, the following Level III recommendation can be made: The use of ONS is a treatment option for patients with medically refractory occipital neuralgia. [7]

European Headache Federation
The purpose of this group is to give an assessment and recommendation for the use of the currently available neuromodulation devices in headache treatment. Because the available data regarding the various stimulation approaches are so scarce and variable, this recommendation is also based on the definition of a clinically significant improvement. In chronic migraines the use of ONS seems acceptable although based on limited evidence. [5]

Studies in the medical literature consist of small case series, retrospective studies and randomized trials with limited patient populations and short follow up. There are no well-designed randomized control trials that compare ONS to established treatment options and clinical trials are ongoing. Some of the studies have indicated that ONS significantly reduced the pain intensity and the number of days with headache in patients with migraine, however, the evidence of ONS efficacy established by randomized controlled trials was limited. Future peer-reviewed studies should optimize and standardize the ONS intervention process. Identification of the responses to various forms of neuromodulation is necessary as well as the efficacy, long-term outcomes and complications resulting from the procedure. [8, 1]

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2015, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
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

CPT® Codes	Description
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or indirect coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

HCPCS Codes	Description
C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter, neurostimulator (implantable)
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable implantable neurostimulator pulse generator
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, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
G43.001-G43.019	Migraine without aura
G43.101-G43.119	Migraine with aura
G43.901-G43.919	Migraine unspecified, intractable

ICD-10-CM Code	Description
G44.001-G44.009	Cluster headache unspecified
G44.011-G44.019	Episodic cluster headache
G44.021-G44.029	Chronic cluster headache
M54.81	Occipital neuralgia
R51	Headache

Reviews, Revisions, and Approvals	Date	Approval Date
Adopted from Health Net NMP#432 Occipital Nerve Stimulation for Headache	11/16	11/16
Reviewed no changes	11/17	11/17
Update no changes	11/18	11/18

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 Mar 20;10(3):e0116786.
2. Hayes, Inc. Health Technology Brief. Electrical Stimulation of the Occipital Nerve for the Treatment of Occipital Neuralgia. January 2014. Archived January 29, 2015.
3. Hayes Medical Technology Directory. Occipital Nerve Stimulation for Chronic Cluster Headache and Chronic Migraine Headache. May 2012. Updated April 28, 2016.
4. Mammis A. Occipital Nerve Stimulation. Medscape. October 14, 2015.
5. Martilletti P, Jensen RH, Antal A, et al. Neuromodulation of chronic headaches: position statement from the European Headache Federation. The Journal of Headache and Pain. October 21, 2013.
6. National Institute for Health and Care Excellence (NICE). Occipital nerve stimulation for intractable chronic migraine. Interventional procedures guidance [IPG452]. April 2013.
7. 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. 2015 Sep; 77 (3):332-41. doi: 10.1227/NEU.
8. Yang Y, Song M, Fan Y, et al. Occipital Nerve Stimulation for Migraine: A Systematic Review. Pain Pract. 2016 Apr;16(4):509-17. doi: 10.1111/papr.12303. Epub 2015 April 2015.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

Rodrigo (2017) reported on the long-term efficacy and tolerability of ONS for medically intractable chronic migraine. A total of 37 individuals were enrolled into the study but 1 individual selected for ONS did not demonstrate a good response during the first phase of the study; thus, he did not undergo the permanent implantation. Study participants were evaluated annually using different scales: pain Visual Analogue Scale (VAS), number of migraine attacks per month, sleep quality, functionality in social and work activities, reduction in pain medication, patient satisfaction, tolerability, and reasons for termination. The average follow-up time was 9.4 ± 6.1 years. A total of 31 of the 37 participants completed the 7-year follow-up period. The authors reported that significant pain reduction was obtained in most participants, and the VAS decreased by 3.8 ± 2.5 points. These results remained stable during the entire follow-up period. The authors also reported that the number of migraine days per month diminished from 17.9 ± 0.1 at baseline to 7.3 ± 7.2 at the last visit. While the ONS treatment was generally well tolerated, 2 subjects, complained of painful stimulation, which was solved by reprogramming. There were 4 cases of lead externalization and 3 cases of infection which all occurred in the generator pocket. A total of 7 of the 35 permanently implanted devices were definitively removed; 2 were removed due to treatment inefficacy and 5 were explanted because the subjects were no longer symptomatic and considered to be cured from their pain, even with the stimulation off. During the course of the study, two implanted generators reached their end-of-life and required replacement. The authors acknowledged that some of the shortcomings of this study include its uncontrolled, open-label design as well as the fact that not all of the participants completed the 7-year follow-up period.

Miller and colleagues (2016) conducted an uncontrolled, open-label, prospective study exploring the long-term efficacy, functional outcome and safety of ONS in 53 individuals suffering with intractable chronic migraine (CM). A total of 53 subjects receiving care between 2007 and 2013 at a single institution were implanted with an occipital nerve stimulator. The participants ranged from 26-70 years of age and had suffered with CM for approximately12 years and had failed a mean of 9 (range 4-19) treatments prior to implantation. Of the 53 participants, 18 had CM in addition to other chronic headache phenotypes. After a median follow-up of 42 months (range 6-97), the monthly moderate-to-severe headache days (that is those days on which pain was more than 4 on the verbal rating score and lasted at least 4 hours) was reduced by 8.5 days ($p<0.001$) in the whole cohort, 5.8 days ($p<0.01$) in those with CM alone and 12.2 days ($p<0.001$) in those with various headache types including CM. Response rate of the study group, defined as a > 30 % reduction in monthly moderate-to-severe headache days, was observed in 45.3 % of the whole cohort, 34.3 % of those with CM alone and 66.7 % in those with various phenotypes including CM headache types.

Significant reductions were also reported in outcome measures such as pain intensity, all monthly headache days, and pain duration. Reported adverse events included one case of infection but no episodes of lead migration.

Dodick and colleagues (2015) reported the 52-week results of their short-term efficacy and safety study of peripheral nerve stimulation (PNS) of the occipital nerves for managing intractable CM. In this multicenter, double-blinded study, 157 participants were initially implanted with a neurostimulation system, randomized 2:1 to an active treatment or sham treatment control group for 12 weeks. After the initial 12-week study period, there was no difference in the percentage of subjects with a 50% reduction in their visual analog score for pain, although pain intensity, headache days and migraine-related disability improved. Participants subsequently received open-label treatment for an additional 40 weeks. A total of 46 (29%) individuals were excluded from the intent-to-treat analysis and 36 (29%) from the intractable CM group, due to loss to follow-up or explantation of the system. At 52 weeks, mean headache days at baseline were 21.6 for the intention-to-treat (ITT) population and 24.2 for a subset of 125 subjects with intractable CM. In the ITT population, headache days decreased by 6.7 days, and by 7.7 (± 8.7) days in the intractable CM population. The percentages of participants who experienced a 30% and 50% reduction in headache days and/or pain intensity were 59.5% and 47.8% respectively. Excellent or good headache relief was reported by 65.4% of the ITT group and 67.9% of the intractable CM group. A total of 68% of the participants were satisfied with the headache relief provided by the neurostimulation system. More than half the subjects in both cohorts were satisfied with the headache relief provided by the device. A total of 183 procedure/device-related adverse events transpired during the study, of which 85 (40.7%) required surgical intervention and 18 (8.6%) required hospitalization; 70% of the participants experienced an adverse event. Some of the participants (18%) experienced persistent pain and/or numbness with the device. The authors concluded that additional research which focuses on the mitigation of adverse events is needed.

Chen and colleagues (2015) conducted a systematic review examining the effectiveness and adverse effects of ONS for CM. A total of five RCTs (total n=402) and seven case series (total n=115) were included in the systematic review. Pooled results from three multicenter RCTs demonstrated that, at 3 months, ONS was correlated with a mean reduction of 2.59 days (95% confidence interval [CI], 0.91 to 4.27, I^2=0%) of prolonged, moderate to severe headache per month compared with a sham control. The authors concluded that though multiple RCTs have demonstrated that ONS is somewhat effective when compared to sham control, the average effect size is modest and may be exaggerated by bias. The authors acknowledge that further measures to reduce the risk of adverse events and revision surgery are needed

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 a headache occurring more than 15 days of the month for at least 3 months.

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%-15% in adult men and from 14%-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.

Hemicrania continua is another type of vascular headache, which causes moderate pain with occasional 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. The headaches occur daily and are continuous with no pain-free periods.

A cluster headache is a vascular headache that 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 to 8 attacks per day may last from weeks to months, usually followed by remission periods when the headache attacks stop completely.

Electrical stimulation to the occipital nerve is used to prevent or reduce the severity and frequency of head and/or neck pain associated with headache disorders, including occipital neuralgia, migraine headaches, and/or cluster-type headaches in patients who have not responded to medication and other conservative therapy. 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 within the subcutaneous tissues at the base of the skull. The procedure requires a subcutaneous incision at the base of the skull (with the tips of the electrodes placed over the occipital nerves) and another subcutaneous incision in the chest wall or abdomen for the pulse generator. This type of peripheral nerve stimulation technique provides continuous or intermittent electrical stimulation to modulate the activity of the occipital nerve(s) and its branches and thereby reducing the severity and frequency of headaches

The 2012 American Academy of Neurology (AAN) evidence-based guideline update: NSAIDs and other complementary treatments for episodic migraine prevention in adults does not mention local injection therapies, ablative treatments, electrical stimulation or neurosurgeries as complimentary treatments for migraine (Holland, et al, 2012).

The American Association of Neurological Surgeons (AANS) patient website states, “Often, occipital neuralgia symptoms will improve or disappear with heat, rest, physical therapy including massage, anti-inflammatory medications, and muscle relaxants. Oral anticonvulsant medications such as carbamazepine and gabapentin may also help alleviate pain. Percutaneous nerve blocks may not only be helpful in diagnosing occipital neuralgia, but can also help alleviate pain. Nerve blocks involve either the occipital nerves or in some patients, the C2 and/or C3 ganglion nerves. It is important to keep in mind that repeat blocks using steroids may cause serious adverse effects.” Surgical intervention (i.e., microvascular decompression, occipital nerve stimulation) may be considered when the pain is chronic, severe and does not respond to conservative treatment” (AANS, 2019).

American Academy of Neurological Surgeons (AANS). Occipital Neuralgia. Accessed May 28, 2019. Available at URL address: http://www.aans.org/Patient%20Information/Conditions%20and%20Treatments.aspx

3. American Headache Society (AHS). Treatment of cluster headache: The American Headache Society evidence-based guidelines. Published 2016. Accessed May 28, 2019. Available at URL address: https://www.americanheadachesociety.org

4. American Headache Society (AHS). The American Headache Society position statement on integrating new migraine treatments into clinical practice. Published 2018. Accessed May 28, 2019. Available at URL address: https://www.americanheadachesociety.org

Bajwa ZH, Smith JH. Preventive treatment of migraine in adults. In: UpToDate, Dashe JF (Ed), UpToDate, Waltham, MA. (Accessed May 28, 2019).