Clinical Policy: Occipital Nerve Stimulation for Headache

Reference Number: CA.CP.MP.432

Coding Implications

Last Review Date: 11/22

Revision Log

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

Description

Occipital nerve stimulation (ONS) is a form of neuromodulation aimed at treating headache and craniofacial pain in individuals who have not responded to medication and other treatment. It delivers a small electrical charge to the occipital nerve and is proposed to have the ability to be tailored to an individual's specific needs as it is reversible and adjustable. Continuous or intermittent stimulation may be used.

Policy/Criteria

I. It is the policy of California Health & Wellness 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 California Health & Wellness that ONS is considered 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. A 4 – 7 day trial is usually performed prior to permanent implantation to insure the individual obtains pain relief. If so, then a permanent device is considered if the individual reports significant improvements in pain and quality of life.

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.

A 2015 systemic review by Sweet et. al. identified 9 small case series (< 15 patients each) assessing the efficacy of occipital nerve stimulation for treating medically refractory occipital neuralgia. Reviewers did not pool study findings. Conclusions cannot be drawn on the impact of occipital nerve stimulation (ONS) on occipital neuralgia due to the lack of randomized controlled trials (RTCs) or other controlled studies.

Wilbrink and colleagues (2021) conducted a randomized, double-blind, multicenter, phase 3, electrical dose-controlled trial to establish whether ONS could serve as an effective treatment for individuals with medically intractable chronic cluster headache. Study participants were randomly assigned to 24 weeks of ONS at either 100% or 30% of the individually determined range between paresthesia threshold and near-discomfort (double-blind study phase). During

weeks 25-48, participants received individually optimized open-label ONS. The primary outcome was the weekly mean attack frequency during weeks 21-24 compared with baseline across all subjects and, if a decrease was shown, to show a group-wise difference. A total of 150 subjects were enrolled and 131 (87%) were randomly assigned to treatment; 65 (50%) participants to 100% ONS and 66 (50%) to 30% ONS. The authors noted that the attack frequency decreased in the both the 100% and 30% stimulation groups. In the masked study phase, 129 adverse events happened with 100% ONS and 95 occurred with 30% ONS. None of the adverse events were unexpected but 17 with 100% ONS and 8 with 30% ONS were categorized as serious, given they required brief hospital admission for minor hardware-related issues. The most common adverse events were localized pain, impaired wound healing, neck stiffness, and hardware damage. While both groups experienced a decline in attack frequency, a placebo effect cannot be excluded given the lack of a non-intervention control group. The authors note that future research should focus on disentangling the underlying mechanism of action.

Moisset and colleagues (2020) conducted a systematic literature review and meta-analysis of randomized control trials on neurostimulation techniques for acute and preventive migraine treatment. All studies included in the analysis had a comparison group with a minimum follow-up period of 4 weeks for preventive treatments and 2 hours for acute treatments. The studies also had a minimum of 10 participants in each treatment group and assessed pain as a primary or secondary outcome. Once identified, two review authors evaluated each study for risk for bias. The authors found that invasive occipital nerve stimulation was effective in migraine prevention and had a large effect size but also had considerable heterogeneity. The authors concluded that although ONS appears to be effective for migraine prevention, larger well-conducted studies are still necessary to confirm the efficacy of this treatment.

A Hayes Technology Assessment (updated in June 2022) regarding the use of occipital nerve stimulation (ONS) for the treatment of chronic migraine (CM) in individuals who have failed to respond to conservative management. In their review of 7 studies, they concluded " ONS appears to have a positive but variable treatment effect on HA outcomes in selected patients, particularly in reductions of frequency and intensity, albeit with a risk of complications that may require additional surgery. This conclusion was based on an overall low-quality body of evidence, which is supported by evidence from multiple RCTs, but which has inconsistent study designs and lack of a defined population. The varying criteria for refractory CM across the included studies reflects the lack of a consensus definition among practitioners in general, which may have resulted in differences in the selected study populations that could have influenced the outcomes."

In a Hayes Technology Assessment (updated October 2022) regarding occipital nerve stimulation (ONS) for the treatment of chronic cluster headaches that failed conservative management found the evidence to be small in size, very low in quality (lack of studies with placebo control) and the reviewed studies provide insufficient evidence in the effectiveness of ONS for the treatment of chronic cluster headaches. Hayes states that the " body of evidence concerning ONS for chronic CH was small in size and very low in quality. One of the reviewed

studies was a comparative cohort study that was rated as poor quality. The other 6 studies were case series that were rated as poor or very poor. The main reason for downgrading the quality of the body of evidence to very low was due to individual study limitations and the small number of patients receiving ONS within the evidence base. Overall quality was determined based on the balance of benefits and harms and was assessed taking into consideration the quality of individual studies; the precision, directness, and consistency of data; and the applicability of data to general practice."

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.

American Association of Neurological Surgeons (AANS) & Congress of Neurological Surgeons Joint Guideline Committees
Based on data derived from this systematic literature review evaluating the use of ONS, the following Level III recommendation was made by the authors (noting that the recommendation is based on evidence from case series, case reports, comparative studies with historical controls, and expert opinion, as well as significantly flawed randomized, controlled trials): The use of ONS is a treatment option for patients with medically refractory occipital neuralgia.

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.

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.

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
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
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
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
Update no changes	11/19	11/19
Updated codes, background and references, no position change	11/20	11/20
Update no changes	11/21	11/21
Added references, no other changes	11/22	11/22

References

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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.