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Subject: Occipital Nerve Stimulation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Occipital nerve stimulation (ONS) delivers a small electrical charge to the occipital nerve in an attempt 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.

Summary and Analysis of Evidence: UpToDate review "Short-lasting unilateral neuralgiform headache attacks: Treatment and prognosis" (Matharu, Cohen, 2024) states "(b)ilateral occipital nerve stimulation was evaluated in a prospective observational study of 31 patients with intractable short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT) or short-lasting unilateral neuralgiform headache attacks with cranial autonomic symptoms (SUNA). At a median follow-up of 45 months, the mean daily attack frequency decreased from baseline by 69 percent. The rate of adverse events was low. Nociceptive pathways in the head involve an important interaction between trigeminal and cervical afferents in the trigeminocervical complex. This mechanism might be involved in the referral of pain from trigeminal to cervical structures. Thus, either greater occipital nerve blockade or stimulation may play a role in modulating these trigeminocervical connections. Though the mechanism of action of the two treatment modalities is poorly understood, they probably work by completely different mechanisms. Greater occipital nerve blockade reduces afferent traffic along the trigeminal-occipital input, while occipital nerve stimulation increases traffic along this pathway and probably acts by bringing about neuroplastic changes in the pain network. Given the small numbers of patients studied, treatment of SUNCT and SUNA with greater occipital nerve procedures (either blockade or stimulation) should be considered investigational." UpToDate review "Occipital neuralgia" (Garza, 2024) states "(p)atients who do not respond to nerve block or to conservative measures should be evaluated in experienced centers for consideration of alternative treatments. Options include botulinum toxin type A injections, pulsed radiofrequency (PRF), or occipital nerve decompression or

stimulation." In addition, "(o)ccipital nerve stimulation has been employed in selected cases of severe occipital neuralgia unresponsive to less invasive measures, but this method should be reserved for use in a pain center with expertise in neuromodulation." UpToDate review "Hemicrania continua" (Garza, Schwedt, 2024) states "therapeutic benefit has been reported with several locally invasive neuromodulatory procedures <including> greater occipital nerve blocks, occipital nerve stimulation <and> vagus nerve stimulation." UpToDate review "Chronic migraine" (Garza, Schwedt, 2024) states "(t)here are inconsistent data from small, randomized trials regarding the benefit of occipital nerve stimulation for the treatment of chronic migraine [99,100]. In the largest trial, there was no significant difference at 12 weeks for the primary endpoint, the percentage of patients who had a ≥50 percent reduction in mean daily pain score in the active compared with the control group [100]. However, there were statistically significant if modest improvements with active stimulation for a number of secondary endpoints, including the percentage of patients with a ≥30 percent reduction in mean daily pain score, and reduction in the mean number of headache days and migraine-related disability. The findings from these reports are limited by concerns about blinding in the control (sham treatment) groups, given that active treatment causes paresthesia, and relatively high rates of complications, including lead migration in 14 to 24 percent of subjects [99-102]." UpToDate review "Cluster headache: Treatment and prognosis" (May, 2024) states "(o)ccipital nerve stimulation (ONS) is a technique using electronic stimulation of subcutaneous electrodes implanted in the bilateral occipital region via an implanted pulse generator. Small observational studies have reported benefit for some patients with cluster headache. Efficacy in observational studies varies from 36 to 90 percent according to specific outcome measures, surgical approaches, and electrode placement. In a study of 131 patients with medically refractory chronic cluster headache, ONS was associated with an improvement in frequency and severity of cluster attacks. At 24 weeks, 45 percent of patients reported at least a 50 percent reduction in attack frequency. However, infection and lead migration may limit the effectiveness of this therapy. Adverse events included localized pain, neck stiffness, lead migration, and electrode damage. Additional data are needed to help guide patient selection, to optimize the stimulation protocol, and to establish long-term safety of device implantation.

Two systematic reviews of the literature on occipital nerve stimulation have been published, both including RCTs and observational studies. Chen et al (2015) identified 5 RCTs and 7 case series with at least 10 patients. Three of the RCTs were industry-sponsored, multicenter, parallel-group trials and 2 were single-center crossover trials. All 5 included a sham control group and one also included a medication management group. Risk of bias was judged to be high or unclear for all trials. Meta-analyses were performed on 2 outcomes. A pooled analysis of 2 trials did not find a significant difference in response rates between active and sham stimulation and a pooled analysis of 3 trials showed a significantly greater reduction in the number of days with prolonged moderate-to-severe headache. Yang et al (2016) identified the same 5 RCTs as Chen in their systematic review. The Yang review only included studies conducted with patients who had migraines for at least 6 months in duration who did not respond to oral medications. In addition to the RCTs, 5 case series met the inclusion criteria. The definition of response rate varied across studies and could include frequency and/or severity of headaches. Response rates in 3 case series with self-reported efficacy were 100% in each, and response rates in the other 2 series were 50% and 89%, respectively. Complication rates in the series ranged from 40% to 100%. Reviewers noted that the case series were subject to biases (eg, inability to control for the placebo effect), that RCT evidence was limited, and that complication rates were high. The most common complications were lead migration (21%) and infection (7%). Saper et al (2011) reported on the

Occipital Nerve Stimulation for the Treatment of Intractable Chronic Migraine Headache trial, which was a multicenter, randomized feasibility study of occipital nerve stimulation for treatment of intractable chronic migraine headache refractory to preventive medical management. The trial evaluated study design and had no primary endpoint. One hundred ten patients were enrolled, and patients who had a positive response to a short-acting occipital nerve block were randomized as follows: 33 to adjustable stimulation, 17 to preset stimulation of 1 min/d, and 17 to medical management. At the 3-month evaluation, the response rate (percentage of patients who achieved ≥50% reduction in number of headache days per month or a ≥3-point reduction in average overall pain intensity vs. baseline) was 39% in the adjustable stimulation group, 6% in the preset stimulation group, and 0% in the medical management group. Twelve (24%) of 51 subjects who had successful occipital nerve stimulation device implantation experienced lead migration and 3 (6%) of the 51 subjects were hospitalized for adverse events (infection, lead migration, nausea). Trial limitations included a short observation period and ineffective blinding of subjects and investigators to treatment groups. Silberstein et al (2012) reported on an industry-sponsored, double-blind trial, regulated by U.S. Food and Drug Administration (FDA) that randomized 157 patients with chronic migraine refractory to preventive medical management in a 2:1 ratio to active or sham stimulation. Intention-to-treat (ITT) analysis revealed no significant differences between groups in the percentage of patients who achieved 50% or greater reduction in visual analog scale scores for pain at 12 weeks (active, 17.1%; control, 13.5%). More patients in the occipital nerve stimulation group had fewer days with headache, less migraine-related disability, and greater pain relief, although benefits were modest. The most common adverse event was persistent implant site pain. Dodick et al (2015) published results from the 52-week open-label extension of this trial. Results were reported for the ITT population and for the 125 patients who met selection criteria for intractable chronic migraine. Twenty-four patients were excluded from analysis due to explantation of the occipital nerve stimulation system (n=18) or loss to follow-up. Mean headache days at baseline were 21.6 for the ITT population and 24.2 for the intractable chronic migraine group. In the ITT population, headache days were reduced by 6.7 days, and a reduction of 50% or more in the number of headache days and/or pain intensity was observed in 47.8% of this group. Seventy percent of patients experienced at least 1 of 183 device-related adverse events, of which 8.6% of events required hospitalization and 40.7% of events required surgical intervention. Eighteen percent of patients had persistent pain and/or numbness with the device. Numerous case series assessing cluster headache were identified, with sample sizes ranging from 10 to 105 patients. The largest of these case series included 105 patients (Leplus et al, 2021) with refractory cluster headache in a French occipital nerve stimulation database. Mean follow-up was 3.7 years; the number of patients with follow-up data ranged from 60 to 93, depending on the outcome. The primary outcome was change in attack frequency. At last follow-up, 69% (64/93) of patients had a reduction of ≥50% in attack frequency, and 73% (68/93) reported at least a 30% reduction in frequency. Overall response rate was 77% (72/93); including 59% of patients who reported excellent response to treatment and 18% who reported mild response; 23% were non-responders. Statistically significant improvements from baseline were also reported for quality of life measures. Adverse events were common, occurring in 64% (67/105) of patients, including need for reoperation in 28% (29/105). Leone et al (2017) published a case series on use of occipital nerve stimulation in 35 patients with chronic cluster headache. This series had the longest follow-up (median, 6.1 years; range, 1.6-10.7 years). Selection criteria included daily or almost daily cluster headache attacks in the past year and resistance of prophylactic drugs. Twenty (66.7%) of the 30 patients in the per protocol analysis had 50% or more reduction in number of headaches per day and were considered responders. In 12 (40%) patients,

improvement was considered stable (ie, ≤3 headache attacks per month). Limitations of the series reporting on cluster headaches included lack of blinding and comparison groups. Vadivelu et al (2012) reported on a series of 22 patients with Chiari malformation and persistent occipital headaches. Of the 22, 15 (68%) had a successful occipital neurostimulator trial and underwent permanent implantation. At a mean follow-up of 18.9 months (range, 6-51 months), 13 (87%) of the 15 patients reported pain relief greater than 50%. Forty percent of patients reported device-related complications requiring additional surgery (lead migration, uncomfortable position of generator, wound infection) during follow-up. Sweet et al (2015) conducted a systematic review that 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 on occipital neuralgia due to the lack of RCTs or other controlled studies.

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 "(t)here 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. 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."

POSITION STATEMENT:

The use of occipital nerve stimulation devices is considered **experimental or investigational** for all indications. There is insufficient clinical peer reviewed literature demonstrating the safety, efficacy, and the effects of occipital nerve stimulation on long-term health outcomes.

BILLING/CODING INFORMATION:

There is no specific CPT code for occipital nerve stimulation. The following codes may be used to describe occipital nerve stimulation.

CPT Coding:

61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	with connection to 2 or more electrode arrays
64553	Percutaneous implantation of neurostimulator electrode array; 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
64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator

REIMBURSEMENT INFORMATION:

Refer to sections entitled **POSITION STATEMENT.**

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Deep Brain Stimulation and Responsive Neurostimulation, 02-61000-24

Vagus Nerve Stimulation, 02-61000-22

OTHER

None.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/24/24.

GUIDELINE UPDATE INFORMATION:

02/15/10	New Medical Coverage Guideline.
02/15/11	Scheduled review, position statement unchanged. Revised description section; added CPT codes 61885, 61886, and 64553; updated references.
01/01/12	Annual HCPCS coding update. Revised 64553, 64555, 64575, 95970 and 95971 descriptors.
02/15/12	Scheduled review, position statement unchanged. Revised description section and updated references.
02/15/13	Scheduled review. Position statement maintained. Revised description and updated references.
01/01/14	Annual HCPCS update. Added L8679. Program Exceptions section updated.
11/01/15	Revision: ICD-9 Codes deleted.
02/15/19	Scheduled review. Position statement maintained. Revised description, CPT coding, HCPCS coding, and related guidelines. Updated references.
10/15/20	Scheduled review. Revised description, maintained position statement and updated references.
01/01/22	Annual CPT/HCPCS coding update. Revised descriptor 64568.
07/15/22	Scheduled review. Maintained position statement. Updated references.

05/25/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.
11/15/24	Scheduled review. Revised description, maintained position statement and updated references.