



Medical Coverage Policy

Effective Date..... 6/15/2021
Next Review Date..... 6/15/2022
Coverage Policy Number 0063

Headache and Occipital Neuralgia Treatment

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Overview

This Coverage Policy addresses ablative treatments, electrical stimulation or neurosurgeries for the treatment of headache (e.g., chronic migraine, chronic cluster or cervicogenic headache) or occipital neuralgia.

Coverage Policy

Each of the following ablative treatments, electrical stimulation or neurosurgeries is considered experimental, investigational or unproven for the treatment of headache (e.g., chronic migraine, chronic cluster or cervicogenic headache) or occipital neuralgia:

- cervical microdecompression surgery (Jho Procedure)
- discectomy and spinal fusion
- electrical stimulation of occipital nerve
- ganglionectomy
- nerve root decompression
- neurectomy
- occipital nerve neurolysis
- pulsed radiofrequency ablation
- resection of the semispinalis capitis muscle

General Background

Headaches are a commonly reported symptom and can be classified as primary or secondary headaches. Primary headaches are not due to another cause (e.g., brain tumor, infection) and are most commonly further classified as migraine and tension-type headaches. Secondary headaches are due to an underlying condition. Occipital neuralgia is a cranial neuropathy characterized by sharp, shooting pains along the pathway of the occipital nerves which can be the result of pinched nerves, muscle tightness in the neck, or head or neck injury. Other causes include: osteoarthritis of the cervical spine, compression of the occipital nerves, tumors affecting the cervical spine, gout, diabetes, blood vessel inflammation, or infection. Numerous treatments or procedures for headaches (e.g., chronic migraine, chronic cluster or cervicogenic headache) and occipital neuralgia have been proposed, with varying levels of success. The consensus on standard treatment does not exist, because of the variability in patient selection and clinical outcomes. Pharmacological treatment with oral analgesics, anti-inflammatory medications, tricyclic antidepressants, and anticonvulsant medications have been used alone or in combination with other treatment modalities. Other treatment methods include the use of a cervical collar during the acute phase; physical therapy with stretching and strengthening exercises; postural training; relaxation exercises; transcutaneous nerve stimulation (TENS); and manual therapy, including spinal manipulation and spinal mobilization (Choi, et al., 2016; Bogduk, et al., 2009; Biondi, 2005, 2001; Martelletti, et al., 2004).

In a review of medical textbooks, commonly used treatments for pain relief from cervicogenic headache and occipital neuralgia include the use of local injected anesthetics, with or without the addition of corticosteroid preparation, to block the affected nerve(s). It is noted that these injections can be used as therapeutic treatment measures for pain relief, although the duration of pain relief varies from hours to months. However, the scientific evidence regarding injection therapy or percutaneous nerve block for occipital neuralgia and cervicogenic headache has been limited (Dinakar, 2016; Peters, 2004; Chavin, 2003).

Pharmacological and alternative treatment modalities are not effective for some individuals, and therefore other methods have been proposed, such as local injections of anesthetics and/or steroids and epidural steroid injections. Botulinum Toxin Type A (Botox® A) has been investigated as a treatment of occipital neuralgia and cervicogenic headaches (Kapural, et al., 2007; Freund, et al., 2000). For information on the coverage of Botox A for the treatment of cervicogenic headache and other types of headaches, please refer to the Cigna Drug and Biologic Coverage Policy, Botulinum Therapy.

Ablative treatments (e.g., pulsed radiofrequency ablation, radiofrequency ablation, radiofrequency neurotomy, radiofrequency denervation, neurolysis, cryodenervation, nerve root rhizotomy) have been investigated and attempt to denervate the occipital and/or upper cervical nerve. Nevertheless, evidence in the medical literature evaluating ablative techniques is limited and improvement in clinical outcomes has not been consistently demonstrated in well-designed clinical studies. Surgical interventions have been investigated as a treatment option to relieve impingement of the nerve root(s) and thereby eliminate symptoms caused by compression and injury to the cervical nerves, including but not limited to, ganglionectomy, nerve root decompression, resection of the semispinalis capitis muscle and cervical microdecompression (Jho Procedure). Surgical removal of muscle or nerve tissue from headache "trigger sites" has been investigated. It has been reported in textbook literature that adverse events of these procedures can be severe and the benefit may be less than robust and short lasting. These procedures have therefore been abandoned for the most part and are now rarely used (Vincent, et al., 2019; Josie, et al., 2018; Garza, et al., 2016; Caruana, et al., 2014; Mathew, 2014; Son, et al., 2013; Zhang,

et al., 2011; Ducic, et al., 2009; Gille, et al., 2004; Wang, et al., 2002; ; Biondi, 2001; Freund, et al., 2000; Jansen, 2000; Reale, et al., 2000; Sjaastad, et al., 2000; van Suijlekom, et al., 2000; Pikus, et al., 1996; Anthony, 1992; Bovim, et al., 1992b; Koch, et al., 1992).

Electrical stimulation (e.g., occipital nerve stimulation, peripheral nerve stimulation, and peripheral nerve field stimulation) has been proposed as a treatment for occipital neuralgia and headaches. Electrical stimulation can be delivered transcutaneously, percutaneously and by using an implantable device. Peripherally implanted nerve stimulation entails the placement of electrodes near or on a selected peripheral nerve such as the occipital nerves at the base of the head. Percutaneous or open implantation of a neurostimulator electrode array is a technique being investigated for treatment of chronic pain such as occipital neuralgia. Electrical stimulation is delivered by an electrode that is placed subcutaneously at the site of maximum pain rather than the site of the nerve and a pulse generator. This technique is also referred to as subcutaneous target stimulation or peripheral nerve field stimulation. Occipital or peripheral nerve stimulation for chronic migraines has been referred to as the Omega Procedure or Reed Procedure®.

For information on the coverage of peripheral nerve destruction using cryoablation or laser, electrical, chemical or radiofrequency ablation for the treatment of occipital neuralgia and headaches, please refer to Cigna Medical Coverage Policy, Peripheral Nerve Destruction for Pain Conditions.

For information on the coverage of peripheral nerve field stimulation for the treatment of chronic pain, please refer to the Cigna Medical Coverage Policy, Peripheral Nerve Destruction for Pain Conditions.

For information on coverage of the Cefaly Supraorbital Transcutaneous Neurostimulator (Cefaly-Technology, Herstal, Belgium) for the treatment of migraine headache, please refer to the Cigna Medical Coverage Policy, Electrical Stimulation and Home Devices.

U.S. Food and Drug Administration (FDA)

Currently, the FDA has not cleared any occipital nerve stimulation devices for the treatment of headache or occipital neuralgia.

Radiofrequency ablation (RFA) is a procedure and, therefore, is not subject to regulation by the FDA. However, the devices used to perform RFA are regulated by the FDA premarket approval process. There are numerous devices listed in the FDA 510(k) database approved for RFA. Two product codes are dedicated to these devices, one for radiofrequency lesion generators (GXD) and one for radiofrequency lesion probes (GXI) (FDA, 2019). Currently no electrical or radiofrequency devices are approved to treat headache or occipital neuralgia.

Literature Review

NeuroSurgery

A number of different surgical procedures (e.g., cervical dorsal root rhizotomy, cervical nerve root decompression, ganglionectomy) have been investigated for the treatment of headache (e.g., chronic migraine, chronic cluster or cervicogenic headache) or occipital neuralgia. Studies primarily in the form of small retrospective case series have reported positive effects of various surgical treatments. However, there were recurrences of pain and varying levels of pain relief and duration. No specific characteristics could be identified that were predictive of a positive outcome or sustained response to treatment. Prospective studies with longer periods of follow-up are needed to confirm the benefits reported in the available studies.

In a retrospective study, Gande et al. (2015) reported on the long-term efficacy of cervical dorsal root rhizotomy (CDR) in the management of patients with refractory medical occipital neuralgia (ON). A retrospective chart review of 75 ON patients who underwent cervical dorsal root rhizotomy was performed. Fifty-five patients were included because they met the International Headache Society's (IHS) diagnostic criteria for ON, responded to CT-guided nerve blocks at the C-2 dorsal nerve root, and had at least one follow-up visit. Telephone interviews were additionally used to obtain data on patient satisfaction. Forty-two patients (76%) were female, and the average age at surgery was 46 years (range 16-80). Average follow up was 67 months (range 5-150). Etiologies of ON included the following: idiopathic (44%), posttraumatic (27%), postsurgical (22%), post-cerebrovascular accident (4%), postherpetic (2%), and postviral (2%). At last follow-up, 35 patients (64%) reported full pain relief, 11 (20%) partial relief, and 7 (16%) no pain relief. The extent of pain relief after CDR was not significantly

associated with ON etiology ($p=43$). Of 37 patients whose satisfaction-related data were obtained, 25 (68%) reported willingness to undergo repeat surgery for similar pain relief, while 11 (30%) reported no such willingness; a single patient (2%) did not answer this question. Twenty-one individuals (57%) reported that their activity level/functional state improved after surgery, 5 (13%) reported a decline, and 11 (30%) reported no difference. The most common acute postoperative complications were infections in 9% ($n=5$) and CSF leaks in 5% ($n=3$); chronic complications included neck pain/stiffness in 16% ($n=9$) and upper-extremity symptoms in 5% ($n=3$) such as trapezius weakness, shoulder pain, and arm paresthesias. The study was limited by its size and lack of control group.

In a retrospective chart review, Pisapia et al. (2012) evaluated 29 patients who had undergone C2 nerve root decompression ($n=11$), C2 dorsal root ganglionectomy ($n=10$), or decompression followed by ganglionectomy ($n=8$) for intractable occipital neuralgia. The overall results stated that 19 of 29 patients (66%) experienced a good or excellent outcome at most recent follow-up. A total of 34% of the patients reported poor outcome in that the headache was unchanged or worse at a mean follow-up of 45 months. Of the 19 patients who completed the telephone questionnaire (mean follow-up 5.6 years), patients undergoing decompression, ganglionectomy, or decompression followed by ganglionectomy experienced similar outcomes. Of 19 telephone responders, 68% rated overall operative results as very good or satisfactory and 37% poor rated overall operative results as unchanged or worse. The study was limited by its size and lack of control group.

In a retrospective chart review, Acar et al. (2008) evaluated 20 patients who had undergone C2 and/or C3 ganglionectomies for intractable occipital pain. Patients were interviewed regarding pain relief, pain relief duration, functional status, medication usage and procedure satisfaction, preoperatively, immediately postoperative, and at follow-up (mean 42.5 months). C2, C3 and consecutive ganglionectomies at both levels were performed on 4, 5, and 11 patients, respectively. All patients reported preoperative pain relief following cervical nerve blocks. Average visual analog scale scores were 9.4 preoperatively and 2.6 immediately after procedure. Ninety-five percent of patients reported short-term pain relief (<3 months). In 13 patients (65%), pain returned after an average of 12 months (C2 ganglionectomy) and 8.4 months (C3 ganglionectomy). Long-term results were excellent, moderate and poor in 20, 40 and 40% of patients, respectively. Cervical ganglionectomy offers relief to a majority of patients, immediately after procedure, but the effect is short lived. The authors reported that cervical ganglionectomy offers relief to a majority of patients, immediately after procedure, but the effect is short lived.

In a retrospective study ($n=10$), Gille et al. (2004) evaluated a new surgical treatment for greater occipital neuralgia consisting of neurolysis of the greater occipital nerve and section of the inferior oblique muscle. All of the patients had pain exacerbated by flexion of the cervical spine. Mean follow-up was 37 months. The results of the treatment were assessed based on: degree of pain on a visual analog scale (VAS) before surgery, at three months, and at last follow-up; consumption of analgesics before surgery and at follow-up; and the degree of patient satisfaction at follow-up. Anatomic anomalies (i.e., hypertrophy of the venous plexus around C2, nerve penetration of the inferior oblique muscle, and degenerative C1–C2 osteoarthritis) were found in three patients. The mean VAS score was 80/100 before surgery and 20/100 at last follow-up. The majority of the patients were satisfied or very satisfied with the operation. Patients reported a decrease in analgesic consumption.

Kapoor et al. (2003) reported in a retrospective study the results of 17 patients with occipital neuralgia who underwent intradural rhizotomies after experiencing positive results from computed tomography (CT) fluoroscopy-guided C2 or C3 nerve root blocks. Immediately after surgery, all patients had complete pain relief. Patients were followed for a mean of 20 months. At follow-up, 11 patients (64.7%) had complete relief of symptoms; two (11.8%) had partial relief, and four (23.5%) had no relief. Of the nine patients who had undergone previous surgery, four reported complete relief (44.4%); four patients (44.4%) reported no relief, and one reported partial relief. Eight out of 16 (50%) reported more activity and function after surgery; however, 25% felt they were either unchanged or less functional than before surgery. There was a trend toward better response to rhizotomy in patients without prior head or neck surgery. The study was limited by its size and lack of control group.

Jansen (2000) reported in a retrospective study the results of three different surgical treatments in 102 patients with cervicogenic headache that had been nonresponsive to physical or drug therapy. A group of 38 patients were treated with C2 ganglionectomy, and 64 patients with demonstrable spinal structural abnormalities were

treated with dorsal or ventral spinal decompression and fusion. Complete relief of pain was reported by 80% of the entire group, and 60–80% relief was experienced by approximately 15% of patients; 6% of patients experienced no relief of pain. Mean duration of pain relief varied: five months for dorsal decompression, 14 months for ventral decompression and 44 months for C2 ganglionectomy.

Other Treatment Modalities

A variety of other therapeutic modalities (e.g., ablative treatments and electrical stimulation of the occipital nerve) have been studied for the treatment of occipital neuralgia and headaches that do not respond to pharmacological and/or physical therapy. Larger studies with longer periods of follow-up are needed to confirm the benefits reported in the available studies.

Ablative: In a retrospective study, Huang et al. (2012) reported on pulsed radiofrequency (PRF) for occipital neuralgia to determine whether any demographic, clinical, or treatment characteristics are associated with success. A total of 102 patients with a primary diagnosis of occipital neuralgia were treated with PRF of the greater and/or lesser occipital nerve. A positive primary outcome was predefined as $\geq 50\%$ pain relief lasting at least three months. The secondary outcome measure was procedural satisfaction. A total of 51% of the patients experienced $\geq 50\%$ pain relief and satisfaction with treatment lasting at least three months. This study was limited by design and lack of long-term outcomes.

In a prospective study, Vanedleren et al. (2010) reported on the results of six months of follow-up in which patients presenting with clinical findings suggestive of occipital neuralgia and a positive test block of the occipital nerves underwent a pulsed radiofrequency procedure of the nerves. Mean scores for pain, quality of life, and medication intake were measured one, two, and six months after the procedure. Pain was measured by the visual analog and Likert scales, quality of life was measured by a modified brief pain questionnaire, and medication intake was measured by a Medication Quantification Scale. Approximately 52.6% of patients reported a score of six (pain improved substantially) or higher on the Likert scale after six months. No complications were reported. This study was limited by design of the study and lack of long-term outcomes.

In a prospective study, Halim et al. (2010) reported on 86 patients who had undergone lateral C1-2 joint pulsed radiofrequency application, for cervicogenic headache in a single pain center. The percentage of patients who had 350% pain relief at two months, six months, and one year were 50% (43/86), 50% (43/86), and 44.2% (38/86), respectively. Long term pain relief at six months and one year were predicted reliably by $\geq 50\%$ pain relief at two months ($p < 0.001$). One patient complained of increased severity of occipital headache lasting several hours. This study was limited by design of the study and lack of long-term outcomes.

In a systematic review, Grandhi et al. (2018) investigated the use of radiofrequency ablation (RFA) and pulsed radiofrequency ablation (PRFA) for the management of cervicogenic headache (CHA). A total of 10 studies met inclusion for review. There were three randomized controlled trials, three prospective trials, and four retrospective trials that were evaluated for the impact of RFA or PRF for CHA. The criteria for inclusion were based on identification of articles discussing cervicogenic headaches which were previously treatment resistant and occurred without any other pathology of the craniofacial region or inciting event such as trauma. The systematic review indicated that RFA and PRFA provide very limited benefit in the management of CHA. The authors reported that although numerous case reports have demonstrated benefit, presently there are no high-quality randomized controlled trials (RCT) and/or strong non-RCTs to support the use of RFA and PRFA in the management of CHA.

Electrical Stimulation: In a prospective observational study, Rodrigo et al. (2017) evaluated the long-term efficacy and tolerability of occipital nerve stimulation (ONS) for medically intractable chronic migraine. All patients ($n=37$) were previously treated with other therapeutic alternatives (e.g., pharmacological drugs, denervation, or physiotherapy). An ONS system was implanted after a positive psychological evaluation and a positive response to a preliminary occipital nerve blockage. 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. Substantial pain reduction was obtained in most patients, and the VAS decreased by 4.9 ± 2.0 points. These results remained stable over the follow-up period. Five of the 35 permanently implanted patients with

migraine attacks at baseline were free from these attacks at their last visits, whereas the pain severity decreased 3.8 ± 2.5 (according to the VAS) in the remaining patients. Seven of the 35 permanent implanted devices were removed: two devices because of treatment inefficacy, and five devices because the patients were asymptomatic and considered to be cured from their pain, even with the stimulation off. The authors reported that the limitations of the current study include its uncontrolled and open-label design. Controlled and larger studies are needed to confirm these results. Additionally, not all patients completed the 7-year follow-up period.

In an uncontrolled, open-label, prospective study (n=53), Miller et al. (2016) reported on the long-term efficacy, functional outcome and safety of occipital nerve stimulation (ONS) in patients with intractable chronic migraine (CM). The participants had CM for approximately 12 years and had failed a mean of nine (range 4-19) treatments prior to implantation. Of the 53 participants, 18 had CM in addition to other chronic headache phenotypes. The authors reported that over 40% of patients with highly intractable complex CM reported sustained clinical benefit after a mean follow-up of four years. Sustained benefit was also seen in those with multiple headache types in addition to CM. Responders showed improvements in functional outcomes and headache related disability. Adverse event rates were low when implants are conducted in specialist centers. The authors reported that there are ongoing concerns over the risk to benefit ratio. Well-designed double-blind controlled trial with long-term follow-up are needed to clarify the position of neuromodulation in chronic migraine.

In a randomized, multicenter controlled study, Dodick et al. (2015) reported the 52 week results of the efficacy and safety of peripheral nerve stimulation (PNS) of the occipital nerves for managing intractable chronic migraine (ICM). A total of 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. Outcomes collected included number of headache days, pain intensity, migraine disability assessment (MIDAS), Zung Pain and Distress (PAD), direct patient reports of headache pain relief, quality of life, satisfaction and adverse events. Statistical tests assessed change from baseline to 52 weeks using paired t-tests. Intent-to-treat (ITT) analyses of all patients (n=157) and analyses of only patients who met criteria for ICM (n=125) were performed. A total of 46 (29%) individuals were excluded from ITT analysis and 36 (29%) from the ICM group, due to loss to follow-up or explantation of the system. Headache days data at baseline and 52-week were available for 111 patients in the ITT population and for 89 patients in the ICM population. At 52 weeks, mean headache days at baseline were 21.6 for the ITT population and 24.2 for a subset of subjects with ICM. In the ITT population, headache days decreased by 6.7 days, and by 7.7 (± 8.7) days in the ICM 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. There were a total of 209 adverse events (AEs), and 111/157 (70.7%) of the implanted patients experienced one or more AE. A total of 85 subjects (40.7%) required surgical intervention and 18 (8.6%) required hospitalization. Some of the participants (18%) experienced persistent pain and/or numbness with the device. The authors reported that although the surgical techniques associated with implantation of PNS devices for occipital nerve stimulation have improved, the complication rates are still high and refinements in both the technology and implantation techniques are required. A follow-up period of at least three years would be ideal for determining the overall sustainability of the therapy as well as the cumulative adverse event profile.

Mekhail et al. (2017) reported 52-week safety and efficacy results from an open-label extension of the above Dodick et al. (2015) randomized, sham-controlled trial for patients with chronic migraine (CM) undergoing peripheral nerve stimulation of the occipital nerves. In this single center, 20 patients were implanted with a neurostimulation system, randomized to an active or control group for 12 weeks, and received open-label treatment for an additional 40 weeks. Outcomes collected included number of headache days, pain intensity, Migraine Disability Assessment (MIDAS), Zung Pain and Distress (PAD), direct patient reports of headache pain relief, quality of life, satisfaction, and adverse events (AEs). Headache days per month were reduced by 8.51 (± 9.81) days. The proportion of patients who achieved a 30% and 50% reduction in headache days and/or pain intensity was 60% and 35%, respectively. MIDAS and Zung PAD were reduced for all patients. Fifteen (75%) of the 20 patients at the site reported at least one AE. A total of 20 AEs were reported from the site. The authors

reported that despite advancements in surgical techniques, AEs with ONS remain prominent, thus warranting further research into both technology and implantation techniques. The authors concluded that their results supported the 12-month efficacy of 20 CM patients receiving peripheral nerve stimulation of the occipital nerves. The significance of this study is limited by the short follow-up period and small sample size.

In a prospective case series study, Melvin et al. (2007) investigate the effectiveness of peripheral nerve stimulation in reducing occipital headache pain. This was a two-week pilot study involving 11 patients evaluated before and after implantation of PNS systems to treat C2-mediated occipital headaches. Most patients (91% and 64% respectively) reported reductions in medication use and numbers of headaches. Patients also reported a reduction in headache symptoms and the impact of headaches on activities. Two adverse events were encountered, one due to a loose connection and, the other caused by lead migration. The study design lacked randomized patient selection and a control group, and its data were collected by clinical staff rather than an independent third party, which could have influenced the patients' responses.

Slavin et al. (2006) analyzed records of 14 patients with intractable occipital neuralgia treated with peripheral nerve stimulation. All of the patients in the study were diagnosed with chronic, intractable occipital neuralgia. Overall, 23 occipital nerves were stimulated in 14 patients. Seventeen trials in 10 patients were considered successful, and those patients had permanent internalization of the stimulator. At the time of the last follow-up examination (mean 22 months), seven patients with implanted peripheral nerve stimulation had adequate pain control. Two patients had their systems explanted because of loss of stimulation effect or significant improvement of pain, and one patient had part of their hardware removed because of infection. The authors stated this study had a large variation between patients in regard to the etiology of their occipital neuralgia; therefore, they were unable to find any correlation between etiology of occipital neuralgia and the outcome of stimulation.

In a systematic review, Yang et al. (2016) evaluated the clinical efficacy and safety of ONS for treating migraine. A total of five randomized controlled trials, four retrospective studies, and one prospective study met the inclusion criteria. Results from the case series and retrospective studies 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. The mean complication incidence of ONS was 66% for the reviewed studies. The authors reported that future clinical studies should optimize and standardize the ONS intervention process and identify the relationship among the surgical process, efficacy, and complications resulting from the procedure.

Chen et al. (2015) conducted a systematic review and meta-analysis to examine the effectiveness and adverse effects of occipital nerve stimulation (ONS) for chronic migraine. A total of five randomized controlled trials (RCTs) (n=402) and seven case series (n=115) met the inclusion criteria. Pooled results from three multicenter RCTs show that ONS was associated with a mean reduction of 2.59 days of prolonged, moderate to severe headache per month at three months compared with a sham control. Results for other outcomes generally favor ONS over sham controls but quantitative analysis was hampered by incomplete publication and reporting of trial data. Lead migration and infections are common and often require revision surgery. The authors reported that while the effectiveness of ONS compared to sham control has been shown in multiple RCTs, the average effect size is modest and may be exaggerated by bias as achieving effective blinding remains a methodological challenge. Measures to reduce the risk of adverse events and revision surgery are needed. Long-term data is limited. Apart from the one year results of one RCT, evidence is available from single-centre case series, which could only provide imprecise estimations with uncertain generalizability.

In a systematic review, Jasper and Hayek (2008) evaluated the strength of evidence that occipital nerve stimulation is an effective treatment of benign headache. Varied types of headache etiologies including migraine, transformed migraine, chronic daily headache, cluster headache, hemicrania continua, occipital neuralgia, and cervicogenic headache have been studied with peripheral nerve field stimulation and found responsive to stimulation of the suboccipital region, known commonly as occipital nerve stimulation. No randomized controlled trials were identified. Occipital nerve stimulation was reportedly successful for 70–100% of patients. The authors reported that reduction of pain in patients with occipital headaches and transformed migraine is significant and rapid with occipital nerve stimulation. No long-term adverse events occurred. Several short-term incidents

occurred including infection, lead displacement, and battery depletion. The authors reported that the body of evidence as a whole is limited.

Professional Societies/Organizations

The Congress of Neurological Surgeons conducted a systematic review of the literature to provide recommendations for the use of occipital nerve stimulation (ONS) for the treatment of patients with medically refractory occipital neuralgia (ON). A multidisciplinary task force of volunteer neurosurgeons and pain management physicians comprised a Guidelines Task Force responsible for the formation of this evidence-based guideline. A total of nine studies met the criteria for inclusion in this guideline. All articles provided Class III Level evidence. Based on the data derived from this systematic literature review, the following Level III recommendation was made: the use of ONS is a treatment option for patients with medically refractory ON (Sweet, et al. 2015).

The American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS) provide the following definitions for evidence classification:

Class I evidence

- Level I recommendation: Evidence from ≥ 1 well-designed, randomized controlled clinical trials, including overview of such trials

Class II evidence

- Level II recommendation: Evidence from ≥ 1 well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies, including less well designed randomized, controlled trial

Class III evidence

- Level III recommendation: Evidence from case series, comparative studies with historical controls, case reports, and expert opinion, as well as significantly flawed, controlled trials

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).

Use Outside of the US

National Institute for Health and Clinical Excellence (NICE) (United Kingdom) NICE Clinical Guidance on Occipital Nerve Stimulation for Intractable Chronic Migraine issued in 2013 states, "The evidence on occipital nerve stimulation (ONS) for intractable chronic migraine shows some efficacy in the short term but there is very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery" (NICE, 2013).

The Eon™ stimulator (St. Jude Medical, Inc.) received CE mark approval in Europe for the treatment of chronic migraines (Hitt, 2012).

The British Association for the Study of Headache (BASH) established guidelines for healthcare professionals in the diagnosis and management of migraine, tension-type, cluster, and medication-overuse headaches in 2010. The guideline cites occipital nerve stimulation as a possible treatment, but it states that occipital nerve stimulation is still under investigation at specialist centers. No specific guidelines were set for occipital nerve stimulation.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven when used to report ablative treatment, electrical stimulation or neurosurgeries for the treatment of headache or occipital neuralgia:

CPT®* Codes	Description
22590	Arthrodesis, posterior technique, craniocervical (occiput-C2)
62281	Injection/infusion of neurolytic substance (eg, alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, cervical or thoracic
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (List separately in addition to code for primary procedure)
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (List separately in addition to code for primary procedure)
63185	Laminectomy with rhizotomy; 1 or 2 segments
63190	Laminectomy with rhizotomy; more than 2 segments
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

CPT®* Codes	Description
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 inductive coupling
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
64716	Neuroplasty and/or transposition; cranial nerve (specify)
64722	Decompression; unspecified nerve(s) (specify)
64744	Transection or avulsion of; greater occipital nerve
64999†	Unlisted procedure, nervous system
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes

†**Note:** Considered Experimental/Investigational/Unproven when used to report ganglionectomy, neurectomy, pulsed radiofrequency ablation of the occipital nerve or percutaneous, open subcutaneous implantation of neurostimulator electrode array(s), or resection of the semispinalis capitis muscle.

HCPCS Codes	Description
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
E0720	Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (tens) device, four or more leads, for multiple nerve stimulation
E0745	Neuromuscular stimulator, electronic shock unit
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
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

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