Medical Coverage Policy

Effective Date.....6/15/2025
Next Review Date.....6/15/2026
Coverage Policy Number..... 0063

Headache, Occipital, and/or Trigeminal Neuralgia Treatment

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Overview

This coverage policy addresses ablative treatments, electrical stimulation or surgical procedures for the treatment of headache (e.g., chronic migraine, chronic cluster or cervicogenic headache) or occipital neuralgia in adults.

This coverage policy also addresses nerve blocks for headache (e.g., chronic migraine, chronic cluster or cervicogenic headache), occipital neuralgia, and trigeminal neuralgia in adults.

Coverage Policy

Each of the following ablative treatments, electrical stimulation or surgical procedures is considered not medically necessary for the treatment of headache (e.g., chronic migraine, chronic cluster or cervicogenic headache) or occipital neuralgia:

- electrical stimulation of occipital nerve
- ganglionectomy
- neurectomy
- pulsed radiofrequency ablation
- resection of the semispinalis capitis muscle
- topical anesthesia of the sphenopalatine ganglion

Each of the following nerve blocks is not covered or reimbursable for the treatment of headache, occipital neuralgia, and trigeminal neuralgia:

- occipital nerve block (CPT 64405)
- trigeminal nerve block (CPT 64400)
- sphenopalatine ganglion block (CPT 64505)

Peripheral nerve blocks of other cranial nerves (e.g., lesser occipital) (CPT 64450) are not covered or reimbursable for the treatment of headaches, occipital neuralgia, and trigeminal neuralgia.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing; transportation and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

About half of the global population is affected by an active headache disorder, predominantly tension-type headache (TTH) and migraine. Migraine headaches occur three times more frequently in women than men. An individual experiencing migraine headache or seeking care for migraine headache may be labeled as drug seeking, a malingerer or one as not able to handle stress. Women have a disproportionately higher burden of than men. Women may be taken less seriously by healthcare providers, have less access to adequate treatment and are more likely to report medication overuse headache (MOH). Under-represented racial and ethnic groups in the U.S. may not receive adequate medical care for headache treatment compared with whites. Even after accounting for demographic and insurance differences, black people are 40% less likely to be treated by a neurologist than whites and are more likely to end up in emergency departments due to undertreated migraine (Tana, et al., 2024).

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).

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, 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 and resection of the semispinalis capitis muscle. 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 (Bajaj, et al., 2021; Vincent, et al., 2019; Jose, 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; 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; 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 Therapy and Devices in a Home Setting.

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.

Topical Anesthesia of the Sphenopalatine Ganglion

The application of topical anesthesia to the sphenopalatine ganglion (SPG) has been proposed as a treatment option for headaches including cluster headaches and migraine (sphenopalatine ganglion block/sphenopalatine nerve block). The SPG is located behind an area of mucosa posterior to the bony structures of the nose and is linked to the trigeminal nerve, the main nerve involved in headache. The topical SPG block targets the mucosa overlying the SPG (American Migraine Foundation, 2016). Several approaches to topical anesthesia of the SPG have been employed including utilizing a cotton pledget or Q-tip soaked with an anesthetic agent passed through a nasal cannula or inserted blindly to the nasopharynx. The anatomical location of the SPG makes this approach difficult to achieve. Adverse events that have been reported include expistaxis and central nervous system infections (Cady, et al., 2015). Several devices have been developed to overcome the difficulty of getting the anesthetic to the SPG.

U.S. Food and Drug Administration (FDA): An example of a device indicated for topical application of anesthesia to the sphenopalatine ganglion is the TX360® Nasal Applicator (Tian Medical Inc., Libertyville, IL). The device is a class I device by the FDA and is exempt from 510(k) requirements.

According to the manufacturer website (Tian Medical, 2025), the single use device is intended for use in adults with intact nasal mucosa to deliver small amounts of fluid (i.e., 0.6mL) to the nasal pathways (e.g., inferior turbinate, superior turbinate, sphenopalatine foramen). Possible complications include nasal passage irritation and nose bleeding. The website also lists the following contraindications:

- "nasal septal deformity (e.g., malformed facial or nasal passages such as cleft lip and palate, choanal atresia (narrowed nasal passages), atrophic rhinitis, rhinitis medicamentosa, septal perforation, nasal/midface trauma, recent nasal/sinus surgery
- bleeding disorder (e.g., Von Willebrand's disease, hemophilia)
- severe respiratory distress
- neoplasm (e.g., Angiofibroma, sinus tumors, granuloma)
- congestion >10 days, high fever, nasal mucosa that is abnormal in color, or complaints of face pain or headaches
- nasal or facial fracture"

Literature Review: There is insufficient evidence to support the effectiveness of topical anesthesia of the sphenopalatine ganglion for the treatment of headache. Studies are primarily in the form of case series and small randomized controlled trials with short-term follow-ups, conflicting results, and fail to compare the therapy to established treatment options (Morgan and Romanello, 2022; Cady, et al., 2015; Schaffer, et al., 2015).

Cady, et al. (2015) conducted a double-blind, placebo-controlled trial to evaluate repetitive transnasal sphenopalatine ganglion block with the Tx360® nasal applicator device for acute treatment of chronic migraine (i.e., 15+ days per month of headache days lasting > 4 hours for at least three months). Patients (n=41) had a mean age of 41.3 years and included 10 males and 31 females. Eighty-three percent were Caucasian, 10% were African American, and 7% were other. Participants were considered for inclusion if they: had an onset of migraine prior to age 50, were able to differentiate migraine from any other headache type, were not taking a migraine preventive or had been taking a preventive for at least 30 days prior to screening and agreed not to change the medication regimen, were female with childbearing potential they agreed to use a

medically acceptable form of contraception as determined by the investigator. Participants were excluded form participation if they: had a nasal, septal, sinus, or midface deformity, trauma, fracture, or surgery; had a bleeding disorder; had respiratory distress; had a neoplasm; had nasal congestion for more than 10 days with fever; used intranasal medications that would be thought to confound the results of the study; were currently using a schedule II narcotic; had recurrent expistaxis; had an allergy to bupivacaine; were known to be pregnant or breastfeeding; had a concurrent cervicogenic headache or occipital neuralgia; or had severe depression or anxiety. The intervention group (n=27) underwent two SPG blocks per week for six weeks utilizing 0.3mL of 0.5% bupivacaine with the Tx360® device. Participants were given a piece of lemon candy to distract from the taste of the medication prior to each procedure. The comparator group (n=13) underwent the same procedure using saline instead of bupivacaine. The primary outcome evaluated was pain measured on a numeric rating scale (NRS) at 15 minutes, 30 minutes, and 24 hours post-procedure for all 12 treatments. Secondary outcomes evaluated included: the change in NRS scores from pre-procedure to 15 minutes, 30 minutes, and 24 hours post-procedure for all 12 treatments; Patient's Global Impression of Change (PGIC) score for all 12 treatments, the need for acute medication usage during the active treatment phase, adverse events, and Headache Impact Test (HIT-6) scores pre-treatment compared to post-final treatment. A 'p' value of 0.1 was considered to be statistically significant. One participant in the comparator group withdrew due to lack of efficacy. Three participants were removed from analysis due to protocol violations. NRS scores were significantly reduced in the bupivacaine group compared to the saline group at all endpoints ($p<0.001$). NRS scores were significantly reduced from baseline in the saline group at 15 and 30 minutes ($p<0.001$) but was not sustained at 24 hours ($p=0.045$). Statistical improvement in PGIC scores were noted in the bupivacaine group compared to the saline group at 30 minutes and 24 hours post–treatment ($p<0.001$ and $p<0.001$ respectively). Non-significant differences were noted between groups for average acute medication usage during the 6-week treatment period ($p=0.80$). HIT-6 scores were statistically improved from baseline compared to the final treatment in the bupivacaine group ($p=0.005$) but not in the saline group ($p=0.13$). The most common adverse events reported in both groups included: mouth numbness, lacrimation, and bad taste. Author noted limitations of the study included; sub-optimal blinding of participants, small sample size, heterogeneity of headache intensity at the time of intervention, and short-term follow-up.

Schaffer, et al. (2015) conducted a randomized, double blind controlled trial (n=93) to evaluate the efficacy of topical sphenopalatine ganglion (SPG) block using the Tx360 device for the treatment of acute frontal headache in patients presenting to the emergency department. Participants ranged in age from 18–65 years old and were mostly female (74%). Participants were eligible for study inclusion if they: had a frontal-based crescendo-onset headache and a normal neurologic examination. Participants were excluded from study participation if they: presented with posterior or occipital region headache, had a fever of >100ºF, had signs of acute or chronic sinusitis, had nuchal rigidity, or had a sudden onset of headache. Patients were also excluded if they: self-medicated for headache pain within the preceding four hours; had bleeding diatheses; were pregnant; had peripheral vascular disease; had HIV; had a history nasal insufflation of illicit drugs; had a nasal septal deformity; had recent nasal surgery; had nasal passage dryness, soreness, or bleeding; or had an allergy to local anesthetics. Participants in the active treatment group (n=41) received topical application of 0.5% bupivacaine to the SPG using the Tx360 device. The comparator group (n=46) underwent the same procedure using normal saline solution (NSS) instead of bupivacaine. The primary outcome evaluated was whether a 50% reduction in pain (assessed via a 100-mm visual analog scale (VAS)) would be achieved in a greater proportion of patients treated with bupivacaine compared to the same procedure performed using NSS. Reduction of pain by > 19-mm on the VAS (considered "minimally significant"), nausea reduction, and the percentage of patients who were pain and nausea free at 24 hours were secondary outcomes assessed. Follow-up occurred at five minutes, 15 minutes, and 24 hours post-procedure. Rescue medication for continued headache pain was offered to participants at the

discretion of the treating physician after 15 minutes. Seventeen participants were either lost to follow-up, withdrew prior to intervention, or were excluded. There was no significant difference noted between the two groups for the percentage of patients achieving a 50% reduction in pain at 15 minutes. There were no significant differences noted between the two groups for: patients reporting any ongoing headache at 15 minutes, percentage of patients who were nausea free at 15 minutes, or median headache scores at 15 minutes. At 24 hours follow-up, 72.2% of patients in the bupivacaine group were headache free compared to 47.5% in the NSS group. Adverse events were reported by 13.9% of participants in the bupivacaine group and 7.5% in the NSS group and included: nasal dryness, runny notes, sore throat, congestion, hoarseness, nosebleed, and runny nose. Author noted limitations of the study included: short-term follow-up, difficulty blinding the participants due to the taste of the medications, participant attrition, and small participant population. Additional high-quality studies with longer-term follow-up and larger patient populations are necessary to adequately evaluate the safety and efficacy of topical SPG block using the Px360 device for treatment of acute frontal headache.

Professional Societies/Organizations: In a 2016 guideline on the treatment of cluster headache, the American Headache Society (AHS) stated that before specific recommendations can be made for or against the use of sphenopalatine ganglion blockade for the treatment of cluster headaches, randomized controlled trials studying the safety and efficacy are needed. The guideline did not discuss the various approaches to SPG blockade such as injection or topical application.

Nerve Blocks

Nerve blocks, including trigeminal, occipital, sphenopalatine ganglion, and peripheral blocks, have been proposed for the treatment of various headaches and neuralgias including but not limited to chronic headache, cervicogenic headache, migraine, trigeminal neuralgia, and occipital neuralgia. Procedural techniques vary but can include the delivery of injected anesthetics, with or without the addition of corticosteroids thereby reducing pain and inflammation. The duration of therapeutic effect varies from hours to months (Nader, et al., 2023; Dinakar, 2016; Peters, 2004; Chavin, 2003).

Literature Review: There is insufficient evidence to support the effectiveness of nerve blocks for the treatment of the various types of headache, migraine, trigeminal neuralgia, or occipital neuralgia. Studies are primarily in the form of observational studies, non-randomized controlled trials, and systematic review and meta-analyses of RCTs that fail to compare the intervention to established treatment options, have small and heterogeneous patient populations, heterogeneous and unclear treatment parameters, short term follow-ups, incomplete data, and inconsistent results. (Mustafa, et al., 2024; Chowdhury, et al., 2023; Evans, et al., 2023; Nader, et al., 2023; Jacques, et al., 2022; Malekian, et al., 2022; Ornello, et al., 2020; Seo, et al., 2020; Zhang, et al., 2018; Dinakar, 2016; Peters, 2004; Chavin, 2003).

Chowdhury, et al. (2023) conducted a double-blind placebo-controlled trial to evaluate the safety and efficacy of greater occipital nerve blockade in the preventive treatment of chronic migraine. Individuals between the ages of 18–65 years old were included (n=44) if they had a diagnosis of chronic migraine (i.e., headache of any duration and severity for ≥15 days/month and headache meeting ICHD-3 criteria for migraine for at least eight days/month during the four weeks of baseline period). Individuals were excluded from participation if they had used migraine preventive drugs in the three months prior to enrollment; were pregnant; had a lidocaine allergy; or had a history of dementia, psychosis, or severe depression. Female sex made up 86.4% of the population in the active group and 95.9% in the control group. The intervention was three injections of 2mL of 2% lidocaine (n=22) at week zero, four, and eight. The comparator was three injections of 2mL of 0.9% saline at week zero, four, and eight (n=22). Change from the baseline mean number of headache days during the last four weeks of the trial was the primary outcome measured. Secondary outcomes measured were the achievement of ≥50% reduction in headache

days from baseline and the mean number of migraine days during the last four weeks of the trial. Total reduction in headache days was significantly greater in the intervention group compared to the control group (7.2 vs 3 respectively) (95%CI: 10.9–5.8 vs 6.7–2.4 respectively; p=0.018). Total reduction in the mean number of migraine days was greater in the active group compared to the control group (6.4 days vs 1.8 days respectively) (95%CI: 9.8–5.8 vs 5.1–1.6 respectively; p=0.003). A greater number of patients in the active group achieved ≥50% reduction in headache days compared to the intervention group (40.9% vs 9.1% respectively) (p=0.024). No serious adverse events were reported. Fourteen participants in the active group and 14 in the control group experienced at least one adverse event related to the trial regimen (e.g., local site bleeding, pain, swelling, dizziness, vasovagal syncope, vertigo, neck pain). Author noted limitations of the study included the predominantly female population preventing generalization of the study and short-term study duration. An additional limitation of the study is the small patient population. Additional studies with long-term follow-up and larger and more diverse patient populations are needed to confirm these results.

Malekian, et al. (2022) conducted a randomized controlled trial to evaluate the efficacy of greater occipital nerve (GON) block in the preventive treatment of episodic migraines without aura using three different injectable drug regimens compared to placebo GON block. Fifty-five individuals were included in the study with a mean age of 40.42 years old and 72.7% of participants were female. Individuals 18–65 years of age were eligible for inclusion in the study if they had a history of migraine without aura with a frequency of at least four attacks per month. Individuals were excluded if they had: <15 headache-free days per month, started or changed prophylactic migraine treatments in the past month, a hypersensitivity to lidocaine or triamcinolone, a history of seizure, a local infection at the injection site, a history of craniotomy, a diagnosis of medication overuse headache, or a migraine disability assessment score of >21. Participants were randomized to one of four groups: triamcinolone (20mg (0.5mL) of triamcinolone and 2mL of saline) (n=10), lidocaine (2.0mL of lidocaine 2% and 0.5mL of saline) (n=16), lidocaine + triamcinolone (20mg (0.5mL) of triamcinolone and 2.0mL lidocaine 2%) (n=13), or 2.5mL of 0.9% saline solution (placebo) (n=16). Individuals underwent a single injection using a 22-guage needle bilaterally at a point that was 2cm lateral on the line that connects the occipital protuberance to the mastoid process and medial to the occipital artery pulse. The number of attacks participants experienced in the four weeks preceding the injection served as the baseline. The primary outcomes were frequency of headaches (the number of attacks in four-weeks). Secondary outcomes assessed were the severity of headaches (Visual Analogue Scale) and duration of headaches (hours). Patients were assessed at baseline, one week, two weeks, and four weeks after the injection. Analysis demonstrated a significant reduction in mean headache severity and duration (p<0.001; p=0.001, respectively) in all four groups. Mean duration of headache was found to be significantly shorter at the first and second week follow up (p=0.003; p=0.007, respectively) but not at the end of the fourth week (p=0.196). Between group differences in headache frequency was not found to be significant (p=0.306) at the end of four weeks compared to baseline. Cutaneous atrophy and alopecia occurred in two participants in the triamcinolone group and one participant in the lidocaine + triamcinolone group. Author noted limitations of the study included the small patient population and the fact that many participants were already undergoing preventive treatments for their migraines. An additional limitation is the short-term follow-up.

Velásquez-Rimachi, et al. (2022) conducted a systematic review, a quantitative meta-analysis of randomized controlled trials (RCTs) (n=4), and a qualitative analysis of randomized controlled trials (n=7) to evaluate the safety and efficacy of greater occipital nerve block (GONB) with or without corticosteroids as adjunctive therapy for the prevention of chronic migraine (CM). There were 224 participants included in the quantitative meta-analysis and 310 participants included in the qualitative analysis whose ages ranged from 18–75 years old. RCTs and longitudinal observational studies evaluating the effects of GONB with local anesthetics alone or combined with

corticosteroids as adjunctive therapy compared to placebo were considered for inclusion. Case reports and series, non-controlled studies, and studies evaluating headaches other than CM were excluded. The most used intervention among the studies included in the qualitative analysis was 0.5% bupivacaine (1.5 or 2 mL) alone or in combination with a corticosteroid (methylprednisolone 20 mg/0.5 mL or triamcinolone 40 mg/mL). The most used comparator was normal saline solution 0.9% injection alone (2 or 2.5 mL) or in combination with 2 to 4% diluted lidocaine (0.25 or 4.5 mL). Primary efficacy outcomes evaluated included change from baseline in headache frequency (reported as number of hours or days) and intensity (measured by any scale) and frequency and intensity of headache in the intervention group compared to the placebo group. Primary safety outcomes evaluated included the number of participants with at least one adverse event and the number of participants with serious adverse events. Reduction in the use of rescue medication (measured as the number of days of consumption or the number of consumptions during a time) was the secondary efficacy outcome evaluated. The number of patients who withdrew from a study because of an adverse event was evaluated as a secondary safety outcome. Follow-up time for studies included in the qualitative analysis ranged from one week to three months. Among the studies included in the qualitative analysis, the authors reported conflicting results:

- one RCT suggested GONB results in a significant change in the frequency of headache from baseline (low certainty of evidence based on GRADE)
- two RCTs suggested uncertain evidence regarding the effect of GONB on headache frequency average (low certainty of evidence)
- three RCTs suggested uncertain evidence about the effect of GONB on headache intensity average (low certainty of evidence)
- two RCTs suggested very uncertain evidence about the effect of GONB on headache frequency average (low certainty of evidence)
- two RCTs suggested that GONB results in little to no difference in headache intensity average (low certainty of evidence)
- two RCTs suggested GONB increases adverse events slightly.

Categorical data for the quantitative meta-analysis was not provided. Conflicting results were observed among the studies included for qualitative analysis for adverse events. In some studies, more adverse events were reported in the comparator groups than the intervention group while another study reported the opposite. A commonly reported adverse event included minor bleeding at the injection site. One study reported a serious adverse event in the comparator group, however the nature of the event was not described by the authors of this review. The authors noted that the overall quality of evidence was "very low" because of a high risk for bias, the small sample sizes, inconclusive data, and the small number of trials. Additional limitations of the study include high rates of patient attrition among the individual studies and heterogeneous study designs making the pooling of data difficult. Additional, high quality RCTs with larger sample sizes are needed to evaluate the safety and efficacy of GONB of CM.

Ornello, et al. (2020) conducted a systematic review of observational studies (n=7) and meta-analysis of randomized controlled trials (RCT) (n=2) and observational studies (n=3) to evaluate the safety and efficacy of greater occipital nerve block (GONB) for the treatment of cluster headache (CH). A total of twelve studies (n=365) were included in the systematic review with ages ranging 15–76 years. The percent of male participants in each study ranged from 63–95%. Due to high between-study heterogeneity, only five out of the 12 studies were included in the meta-analysis. Studies were included if they evaluated GONBs for the treatment of episodic or chronic CH. Case reports, editorials, letters, reviews, commentaries, abstracts, and studies evaluating multiple cranial nerve blocks were excluded. The primary outcomes measured included: freedom from pain; duration of pain relief; partial relief from pain; reduction in attack frequency, duration, and intensity; headache worsening; and adverse events. Follow-up ranged from 1–90 days. The percent of participants who experienced freedom from pain ranged from 0–90% and those who achieved partial freedom from pain ranged from 1–44%. The pooled proportion of pain-

free subjects at 1 month was 50 % (95 % CI: 24 % to 76 %) with considerable heterogeneity (I2 = 88 %; p < 0.01). Pooled data from the two RCTs demonstrated that GONB resulted in non-statistically significant improvement in freedom from pain at one month compared to controls (p=0.3914). Significant mean reductions in pain intensity (53–85%), CH attack duration (46–67%), and the number of daily CH attacks (60–92%) were observed however, due to variability of time points, formal meta-analysis could not be performed. Injection site pain was the most reported adverse event (7–86%) however, two studies reported on a total of nine participants who experienced transient headache worsening. Author noted limitations of the review included: the small number of RCTs, small patient populations, heterogeneity of the patient populations and treatment parameters, subjective data reports, the effect of oral preventive treatment on the intervention, and possible publication bias. Authors pointed to the need for large, well-designed RCTs to further assess the safety and efficacy of GONB for the treatment of CH.

Seo et al. (2020) conducted a non-randomized controlled trial to evaluate the safety and efficacy of trigeminal nerve block (TNB) in elderly patients with trigeminal neuralgia (TN) at a single outpatient clinic. Participants (n=21) ranged in age from 65–82 years. There were 13 women in the study. Participants were included if they were treated for TN with symptoms refractory to medication. The intervention consisted of TNB using 1mL of bupivacaine. Patients were maintained on their medication throughout the follow-up period. The outcome measure was subjective pain assessment using the numeric rating scale (NRS). Follow-up occurred in two-week intervals for a total of six weeks. A 78% mean reduction in the NRS score was reported two weeks after TNB injection. The authors reported that the best effect was seen at two weeks post injection at which point the NRS score began to increase with the total duration of pain improvement lasting four weeks in 12 participants and six weeks in two participants. There were no adverse events reported. Author noted limitations included the small patient population and heterogeneity of medication regimens. An additional limitation of the study is the unknown effect of medication use on the intervention. The authors pointed to a need for further studies with larger patient populations to objectively analyze the treatment effect and duration of TNB on TN.

In a systematic review and meta-analysis of RCTs (n=7), Zhang, et al. (2018) evaluated the safety and efficacy of GONB on the treatment of migraine. The average age of participants (n=323) ranged from 35–44 years. Individual study sample sizes ranged from 23–72 participants. RCTs were included if the study population was diagnosed with migraine and if GONB with bupivacaine, corticosteroids, and/or lidocaine served as the intervention and sham GON injection with saline, lidocaine, or bupivacaine served as the comparator. The primary outcome measured was pain intensity. Secondary outcomes included: analgesic medication consumption, headache duration, and adverse events. Analysis revealed that a significant reduction in pain intensity (p=0.0005) and analgesic medication consumption (p=0.02) occurred in the GONB group when compared to the control group. A non-significant reduction in headache duration (p=0.06) was observed in the GONB group compared to the control group. There were no significant increases in adverse events in the GONB group compared to the control group (p=0.80). Author noted limitations of the study include heterogeneity of treatment parameters, small patient populations, and short follow-up duration.

Professional Societies/Organizations: In a 2016 guideline on the treatment of cluster headache, the American Headache Society gave a level A recommendation (established as effective) for the use of suboccipital steroid injection for transitional prophylactic therapy (i.e., short-term or bridge therapy) for episodic and chronic cluster headache. Two studies were referenced to support this recommendation where the injections were performed as add-on therapy to initiation or escalation of verapamil.

Peripheral nerve blocks are not addressed in the 2018 American Headache Society position statement on integrating new migraine treatments into clinical practice. However, the 2021

update (Ailani, et al., 2021) to the position statement states that when acute treatment does not bring relief, office-based options such as, parenteral formulations of triptans, DHE, antiemetics, NSAIDs (e.g., ketorolac), anticonvulsants (e.g., valproate sodium [not in women of childbearing potential who are not using an appropriate method of birth control]), corticosteroids, magnesium sulfate, and peripheral nerve blocks should be considered.

The 2019 practice guideline on acute treatment of migraine in children and adolescents from the subcommittee of the American Academy of Neurology and the American Headache Society does not address peripheral nerve blocks (Oskoui, et al., 2019).

NeuroSurgery

A number of different surgical procedures (e.g., 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 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.

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: Jain et al. (2024) conducted a systematic review of 13 retrospective studies, 9 prospective studies, 3 case series, 2 case reports, and 5 randomized control studies to evaluate the safety and efficacy of radiofrequency ablation (RFA) for the treatment of chronic headache pain. Sample sizes for the individual studies ranged from 1–211 participants with ages ranging from 27–63 years old. Individual study follow-up times were not specified. Types of headache treated included: cervicogenic, episodic, chronic cluster, migraine, hemicrania continua, and occipital neuralgia. Targeted nerves and ablation techniques used varied between studies (e.g., C1-C2 joint, sphenopalatine, C2 cervical nerve root, medial branch of posterior primary ramus at C3-C4; pulsed vs continuous). The primary outcomes were mean pain improvement assessed by the visual analog scale or numeric rating scale, mean duration of improvement, and side effects. Functional, physical disability, and patient satisfaction scores were analyzed if available. Treatment results were varied between studies. The authors suggested that RFA "can reduce pain scores, provide lasting pain relief, increase function, and increase patient satisfaction in both the short- and long-term [i.e., 4–9 months]". Side effects varied and included: hypo-esthesia, nausea, dizziness, epistaxis, hematoma, hypertension, arthrolithiasis, ophthalmoparalysis, facial numbness, masseter weakness, transient neck torticollis, temporary worsening of cluster and occipital headache frequency and intensity, and ataxia. Author noted limitations included: retrospective nature of most included studies and lack of consistency of approach and targeted nerves. Additional limitations included the lack of statistical analysis of the data, incomplete data, and inconsistent results.

Orhurhu et al. (2021) conducted a systemic review of six randomized controlled trials (RCT), six prospective studies, and six retrospective studies to summarize the available evidence for the safety and efficacy of radiofrequency ablation (RFA) for treatment of headache (i.e., neuralgia-associated, nasal obstruction, occipital neuralgia, cluster headache, occipital headache, cervicogenic headache, chronic migraine). Individual study sample sizes ranged from 12–168 patients and the age of participants ranged from 33.8–54 years old. Studies were included in the review if they were original studies that evaluated the application of either continuous or pulsed RFA for the treatment of headache lasting for at least one month in adults. Case reports, studies with an unclear diagnosis, and studies evaluating children were excluded. The occipital nerve was the most commonly targeted nerve followed by three studies that targeted the sphenopalatine ganglion. Most of the studies evaluated pain as the primary outcome measure using the Visual Analog Scale or Numeric Rating Scale. Secondary outcome measures included: reduction in analgesic intake postprocedure, the need for repeat procedures, and complications. The longest follow-up was one year. Overall, pain outcomes were either significantly improved or equally as effective as the comparator (i.e., turbinoplasty, steroid injections, sham RFA). However, one RCT observed that improvements in pain ceased to be significant compared to steroid injections at six months. Eight of the studies demonstrated short-term pain relief (i.e., pain reduction lasting up to 12 weeks) and eight of the studies demonstrated long-term pain relief (i.e., pain reduction lasting for greater than 12 weeks). Non-significant improvements in pain were noted with continuous RFA compared to pulsed RFA. Adverse events included: eyelid swelling; rash; superficial infection of the procedure site; worsening of headache; and paresthesias of the neck, upper gums, and cheek. Author noted limitations of the study included: heterogeneity of study designs, intervention technique, and headache etiologies; patient selection bias; and short-term follow-up.

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 ≥ 50% pain relief lasting at least three months. The secondary outcome measure was procedural satisfaction. A total of 51% of the patients experienced ≥ 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 ≥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: Wilbrink, et al. (2021) conducted a randomized, double-blind, multicenter, controlled trial to evaluate the safety and efficacy of occipital nerve stimulation (ONS) on medically intractable chronic cluster headache (MICCH). There was a total of 131 participants included in the trial with 66 of them allocated to the comparator group and 65 to the intervention group. The mean age of all participants was 44 years old with 36% of participants being female. Participants were included if they had: chronic cluster headache; at least four attacks per week; minimum age of 18 years; a brain MRI completed within the past year without relevant findings (i.e., lesions that were probably related to cluster headache); non-response, intolerance, or contraindication to verapamil and lithium treatment in the past; along with non-response, intolerance, or contraindication to methysergide, topiramate, or gabapentin. Participants were excluded if they were pregnant, had a cardiac pacemaker or other neuromodulatory device, had a psychiatric or cognitive disorder, a history of serious drug habituation or overuse of acute-headache medication, or previous destructive surgery involving the C2 or C3 vertebrae or deep brain stimulation. The study consisted of several phases: a 12 week baseline observation period; a

device implantation and 10-day 10% ONS run-in treatment period; a 24-week randomized, double-blind ONS treatment period with stepwise increase of ONS intensity in both treatment groups (Intervention group goal: 100%, comparator group goal: 30%); and a 24-week open-label ONS individually optimized treatment period. Due to difficulty masking the treatment, the comparator group was administered ONS at a reduced intensity (30%) which, the authors theorized would still produce occipital paresthesia and mitigate the risk of unmasking while allowing for differential efficacy. The mean attack frequency (MAF) per week during weeks 21–24 (i.e., blinded study period) served as the primary outcome. Secondary outcomes evaluated included: MAF for each 4-week period, weekly mean attack intensity (0–10 on the numeric rating scale) at weeks 21–24 and weeks 45–48, proportion of participants with > 50% and > 30% reduction in MAF (i.e., "responder") at week 24 and week 48 compared with baseline, patient satisfaction at week 24 and 48 by asking the patients whether they would recommend ONS to other patients with MICCH on a 5-point Likert scale, use of acute attack medication, presumed treatment allocation, analysis to identify people most likely to be responders, awareness of paraesthesias, economic evaluation (i.e., comparison between the costs and outcomes of healthcare interventions), and adverse events. Follow-up occurred at various points including four, 24, and 48 weeks. Each treatment arm lost one patient to follow-up at 24 weeks. Each treatment arm lost 11 participants to follow-up at 48 weeks. All analyses were done by intention to treat. One patient was excluded from the intention to treat analysis because he did not receive the implant on the day of surgery. At 21–24 weeks, the median MAF per week decreased in the total population, intervention group, and control group by 5.21 ($p<0.0001$), 4.08, and 6.50 attacks, respectively. At 45–48 weeks, the median MAF per week decreased in the total population receiving open-label individually optimized ONS by 5.92 attacks. The percentage of participants who achieved a 50% reduction in MAF at 24 and 48 weeks was 44.6% and 50% respectively. There was no difference in the percentage of participants who achieved a 30% reduction in MAF at 24 and 48 weeks (55.4%). Data for the change from baseline in mean attack intensity at all time points was not reported as separate values for each treatment group. Instead, total population data was provided demonstrating a reduction in mean attack intensity from baseline at four, 24, and 48 weeks (1.62, 2.01, and 2.44 respectively). A total of 59 serious adverse events were reported. Thirty-five events were related to hardware problems. The most serious adverse event reported was a right-middle cerebral artery transient ischemic attack one month and 15 days after implantation that was considered not to be related to the intervention. An author noted limitation of the study was the fact that 20 participants in the intervention group had to undergo a reduction in the prespecified ONS intensity due to discomfort. Additional limitations included patient attrition and incomplete data reporting. Additional, larger, well-designed studies are needed to evaluate the safety and efficacy of ONS for the treatment of MICCH.

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 was 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) investigated 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 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
Department of Veterans Affairs and the Department of Defense (VA/DoD): In a 2023 clinical practice guideline on the treatment of headache, the Department of Veterans Affairs and the Department of Defense (VA/DoD) stated that there was insufficient evidence to support a recommendation for or against the use of pulsed radiofrequency or sphenopalatine ganglion block for the treatment of headache. The body of evidence was found to be of low quality and limited by small sample sizes.

Congress of Neurological Surgeons (CNS): The CNS 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). In 2023, the CNS published an update to this recommendation based on a literature review through 2023 that included six studies of class III level of evidence. These studies did not change the previous recommendation. The authors concluded "the overall level of evidence remains low because of the lack of commercially available dedicated craniofacial PNS devices, of insurance coverage for many patients, and of trials specifically designed to evaluate neuromodulation for craniofacial pain" (Staudt, et al., 2023).

American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS): The AANS and 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

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	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.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Not Medically Necessary when used to report ablative treatment, electrical stimulation or surgical procedures for the treatment of headache or occipital neuralgia:

CPT®* Codes	Description
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64744	Transection or avulsion of; greater occipital nerve
64999†	Unlisted procedure, nervous system

†**Note: When used to report ganglionectomy, neurectomy, pulsed radiofrequency ablation of the occipital nerve or percutaneous, open subcutaneous implantation of neurostimulator electrode array(s), resection of the semispinalis capitis muscle, or topical anesthesia of the sphenopalatine ganglion.**

HCPCS Codes	Description
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system

HCPCS Codes	Description
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

Not covered or reimbursable when used to report nerve blocks for all indications, including peripheral nerve blocks of other cranial nerves (e.g., lesser occipital) for the treatment of headaches, occipital neuralgia, and trigeminal neuralgia.:

CPT®* Codes	Description
64400	Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie, ophthalmic, maxillary, mandibular)
64405	Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch
64505	Injection, anesthetic agent; sphenopalatine ganglion

ICD-10-CM Diagnosis Codes	Description
B02.22	Postherpetic trigeminal neuralgia
G43.001	Migraine without aura, not intractable, with status migrainosus
G43.009	Migraine without aura, not intractable, without status migrainosus
G43.011	Migraine without aura, intractable, with status migrainosus
G43.019	Migraine without aura, intractable, without status migrainosus
G43.101	Migraine with aura, not intractable, with status migrainosus
G43.109	Migraine with aura, not intractable, without status migrainosus
G43.111	Migraine with aura, intractable, with status migrainosus
G43.119	Migraine with aura, intractable, without status migrainosus
G43.401	Hemiplegic migraine, not intractable, with status migrainosus
G43.409	Hemiplegic migraine, not intractable, without status migrainosus
G43.411	Hemiplegic migraine, intractable, with status migrainosus

ICD-10-CM Diagnosis Codes	Description
G43.419	Hemiplegic migraine, intractable, without status migrainosus
G43.501	Persistent migraine aura without cerebral infarction, not intractable, with status migrainosus
G43.509	Persistent migraine aura without cerebral infarction, not intractable, without status migrainosus
G43.511	Persistent migraine aura without cerebral infarction, intractable, with status migrainosus
G43.519	Persistent migraine aura without cerebral infarction, intractable, without status migrainosus
G43.601	Persistent migraine aura with cerebral infarction, not intractable, with status migrainosus
G43.609	Persistent migraine aura with cerebral infarction, not intractable, without status migrainosus
G43.611	Persistent migraine aura with cerebral infarction, intractable, with status migrainosus
G43.619	Persistent migraine aura with cerebral infarction, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.A0	Cyclical vomiting, in migraine, not intractable
G43.A1	Cyclical vomiting, in migraine, intractable
G43.B0	Ophthalmoplegic migraine, not intractable
G43.B1	Ophthalmoplegic migraine, intractable
G43.C0	Periodic headache syndromes in child or adult, not intractable
G43.C1	Periodic headache syndromes in child or adult, intractable
G43.D0	Abdominal migraine, not intractable
G43.D1	Abdominal migraine, intractable
G43.801	Other migraine, not intractable, with status migrainosus
G43.809	Other migraine, not intractable, without status migrainosus
G43.811	Other migraine, intractable, with status migrainosus
G43.819	Other migraine, intractable, without status migrainosus
G43.821	Menstrual migraine, not intractable, with status migrainosus
G43.829	Menstrual migraine, not intractable, without status migrainosus
G43.831	Menstrual migraine, intractable, with status migrainosus
G43.839	Menstrual migraine, intractable, without status migrainosus
G43.901	Migraine, unspecified, not intractable, with status migrainosus
G43.909	Migraine, unspecified, not intractable, without status migrainosus
G43.911	Migraine, unspecified, intractable, with status migrainosus
G43.919	Migraine, unspecified, intractable, without status migrainosus
G43.E01	Chronic migraine with aura, not intractable, with status migrainosus
G43.E09	Chronic migraine with aura, not intractable, without status migrainosus
G43.E11	Chronic migraine with aura, intractable, with status migrainosus
G43.E19	Chronic migraine with aura, intractable, without status migrainosus
G44.001	Cluster headache syndrome, unspecified, intractable
G44.009	Cluster headache syndrome, unspecified, not intractable

ICD-10-CM Diagnosis Codes	Description
G44.011	Episodic cluster headache, intractable
G44.019	Episodic cluster headache, not intractable
G44.021	Chronic cluster headache, intractable
G44.029	Chronic cluster headache, not intractable
G44.031	Episodic paroxysmal hemicrania, intractable
G44.039	Episodic paroxysmal hemicrania, not intractable
G44.041	Chronic paroxysmal hemicrania, intractable
G44.049	Chronic paroxysmal hemicrania, not intractable
G44.051	Short lasting unilateral neuralgiform headache with conjunctival injection and tearing (SUNCT), intractable
G44.059	Short lasting unilateral neuralgiform headache with conjunctival injection and tearing (SUNCT), not intractable
G44.091	Other trigeminal autonomic cephalgias (TAC), intractable
G44.099	Other trigeminal autonomic cephalgias (TAC), not intractable
G44.1	Vascular headache, not elsewhere classified
G44.201	Tension-type headache, unspecified, intractable
G44.209	Tension-type headache, unspecified, not intractable
G44.211	Episodic tension-type headache, intractable
G44.219	Episodic tension-type headache, not intractable
G44.221	Chronic tension-type headache, intractable
G44.229	Chronic tension-type headache, not intractable
G44.301	Post-traumatic headache, unspecified, intractable
G44.309	Post-traumatic headache, unspecified, not intractable
G44.311	Acute post-traumatic headache, intractable
G44.319	Acute post-traumatic headache, not intractable
G44.321	Chronic post-traumatic headache, intractable
G44.329	Chronic post-traumatic headache, not intractable
G44.40	Drug-induced headache, not elsewhere classified, not intractable
G44.41	Drug-induced headache, not elsewhere classified, intractable
G44.51	Hemicrania continua
G44.52	New daily persistent headache (NDPH)
G44.53	Primary thunderclap headache
G44.59	Other complicated headache syndrome
G44.81	Hypnic headache
G44.82	Headache associated with sexual activity
G44.83	Primary cough headache
G44.84	Primary exertional headache
G44.85	Primary stabbing headache
G44.86	Cervicogenic headache
G44.89	Other headache syndrome
G50.0	Trigeminal neuralgia
G50.1	Atypical facial pain
G50.8	Other disorders of trigeminal nerve
G50.9	Disorder of trigeminal nerve, unspecified
G97.1	Other reaction to spinal and lumbar puncture
M54.81	Occipital neuralgia

ICD-10-CM Diagnosis Codes	Description
O29.40	Spinal and epidural anesthesia induced headache during pregnancy, unspecified trimester
O29.41	Spinal and epidural anesthesia induced headache during pregnancy, first trimester
O29.42	Spinal and epidural anesthesia induced headache during pregnancy, second trimester
O29.43	Spinal and epidural anesthesia induced headache during pregnancy, third trimester
O74.5	Spinal and epidural anesthesia-induced headache during labor and delivery
O89.4	Spinal and epidural anesthesia-induced headache during the puerperium
R51.0	Headache with orthostatic component, not elsewhere classified
R51.9	Headache, unspecified
T88.59XA	Other complications of anesthesia, initial encounter
T88.59XD	Other complications of anesthesia, subsequent encounter
T88.59XS	Other complications of anesthesia, sequela

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	Removed policy statements for: • Nerve root decompression • Occipital nerve neurolysis	6/15/2025
Focused Review	Removed policy statements for: • cervical microdecompression surgery (Jho Procedure) • discectomy and spinal fusion	11/1/2024
Annual Review	No clinical policy statement changes.	6/15/2024