Anthem

Medical Policy

Subject: Implantation of Occipital, Supraorbital or Trigeminal Nerve Stimulation Devices (and Related Procedures)
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Description/Scope

This document addresses the implantation of, and procedures related to, occipital, supraorbital and trigeminal nerve stimulation devices.

The implantation of these nerve stimulation devices involves the surgical implantation of a permanent device to deliver small electrical impulses to the occipital, supraorbital or trigeminal nerves.

Occipital and supraorbital nerve stimulation have been proposed for pain management associated with occipital neuralgia, chronic headaches and migraines refractory to medical treatments. Trigeminal nerve stimulation is being explored as a treatment for various conditions including but not limited to trigeminal neuralgia and depression.

For information on transcutaneous supraorbital nerve stimulation for migraine headaches (that is, the Cefaly device), refer to DME.00011 Electrical Stimulation as a Treatment for Pain and Other Conditions: Surface and Percutaneous Devices.

Position Statement

Investigational and Not Medically Necessary:

Implantation of an occipital nerve stimulation device (and related procedures) is considered**investigational and not medically necessary** for all indications.

Implantation of a supraorbital nerve stimulation device (and related procedures) is considered**investigational and not medically necessary** for all indications.

Implantation of a trigeminal nerve stimulation device (and related procedures) is considered**investigational and not medically necessary** for all indications.

Rationale

Occipital Nerve Stimulation (ONS)

ONS is accomplished via a modified device related to a spinal cord stimulator and is one type of implantable pulse generator (IPG). ONS is used to stimulate the occipital nerve, which is responsible, in part, for carrying signals from cranial pain conditions such as migraines and chronic headaches. Treatment for occipital pain commonly includes the use of medications or anesthetic blocks. While this type of treatment may work in some instances, pain relief may be short lived or not relieved in some individuals. For severe cases of cranial pain conditions, direct treatment of the occipital nerve has been studied.

Wilbrink and colleagues (2021) conducted a randomized, double-blind, multicenter, phase 3, electrical dose-controlled trial to establish whether ONS could serve as an effective treatment for individuals with medically intractable chronic cluster headache. Study participants were randomly assigned to 24 weeks of ONS at either 100% or 30% of the individually determined range between paresthesia threshold and near-discomfort (double-blind study phase). During weeks 25-48, participants received individually optimized open-label ONS. The primary outcome was the weekly mean attack frequency during weeks 21-24 compared with baseline across all subjects and, if a decrease was shown, to show a group-wise difference. A total of 150 subjects were enrolled and 131 (87%) were randomly assigned to treatment; 65 (50%) participants to 100% ONS and 66 (50%) to 30% ONS. One of the 66 subjects assigned to 30% ONS was not implanted and was therefore excluded from the intention-to-treat analysis. Because the weekly mean attack frequencies at baseline were skewed (median 15.75; IQR 9.44 to 24.75) the authors used log transformation to analyze the data. In the 100% ONS stimulation group, mean attack frequency declined from 17.58 (9.83 to 29.33) at baseline to 9.50 (3.00 to 21.25) at 21-24 weeks (median change from baseline -4.08, -11.92 to -0.25), and for the 30% ONS stimulation group, mean attack frequency declined from 15.00 (9.25 to 22.33) to 6.75 (1.50 to 16.50; -6.50, -10.83 to -0.08). The difference in median weekly mean attack frequency between cohorts at the end of the masked phase in weeks 21-24 was -2.42 (95% confidence interval [CI], -5.17 to 3.33). In the masked study phase, 129 adverse events happened with 100% ONS and 95 occurred with 30% ONS. None of the adverse events was unexpected but 17 with 100% ONS and 8 with 30% ONS were categorized as serious, given they required brief hospital admission for minor hardware-related issues. The most common adverse events were localized pain, impaired wound healing, neck stiffness, and hardware damage. While both groups experienced a decline in attack frequency, a placebo effect cannot be excluded given the lack of a non-intervention control group. The authors note that future research should focus on disentangling the underlying mechanism of action.

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

Rodrigo (2017) reported on the long-term efficacy and tolerability of ONS for medically intractable chronic migraine. A total of 37 individuals were enrolled into the study but 1 individual selected for ONS did not demonstrate a good response during the first phase of the study and did not undergo the permanent implantation. Study participants were evaluated annually using different scales: pain Visual Analogue Scale (VAS), number of migraine attacks per month, sleep quality, functionality in social and work activities, reduction in pain medication, patient satisfaction, tolerability, and reasons for termination. The average follow-up time was 9.4 ± 6.1 years. A total of 31 of the 37 participants completed the 7-year follow-up period. The authors reported that significant pain reduction was obtained in most participants, and the VAS decreased by 3.8 ± 2.5 points. These results remained stable during the entire follow-

up period. The authors also reported that the number of migraine days per month diminished from 17.9 ± 0.1 at baseline to 7.3 ± 7.2 at the last visit. While the ONS treatment was generally well tolerated, 2 subjects complained of painful stimulation, which was solved by reprogramming. There were 4 cases of lead externalization and 3 cases of infection which all occurred in the generator pocket. A total of 7 of the 35 permanently implanted devices were definitively removed; 2 were removed due to treatment inefficacy and 5 were explanted because the subjects were no longer symptomatic and considered to be cured from their pain, even with the stimulation off. During the course of the study, two implanted generators reached their end-of-life and required replacement. The authors acknowledged that some of the shortcomings of this study include its uncontrolled, open-label design as well as the fact that not all of the participants completed the 7-year follow-up period.

Miller and colleagues (2016) conducted an uncontrolled, open-label, prospective study exploring the long-term efficacy, functional outcome and safety of ONS in 53 individuals suffering with intractable chronic migraine (CM). A total of 53 subjects receiving care between 2007 and 2013 at a single institution were implanted with an occipital nerve stimulator. The participants ranged from 26-70 years of age and had suffered with CM for approximately 12 years and had failed a mean of 9 (range 4-19) treatments prior to implantation. Of the 53 participants, 18 had CM in addition to other chronic headache phenotypes. After a median follow-up of 42 months (range 6-97), the monthly moderate-to-severe headache days (that is those days on which pain was more than 4 on the verbal rating score and lasted at least 4 hours) was reduced by 8.5 days ($p<0.001$) in the whole cohort, 5.8 days ($p<0.01$) in those with CM alone and 12.2 days ($p<0.001$) in those with various headache types including CM. Response rate of the study group, defined as a > 30 % reduction in monthly moderate-to-severe headache days, was observed in 45.3 % of the whole cohort, 34.3 % of those with CM alone and 66.7 % in those with various phenotypes including CM headache types. Significant reductions were also reported in outcome measures such as pain intensity, all monthly headache days, and pain duration. Reported adverse events included one case of infection but no episodes of lead migration.

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

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

Serra and Marchioretto (2012) conducted a randomized crossover study to investigate the safety and efficacy of ONS for CM and medication overuse headache (MOH) in individuals and to evaluate changes in disability, quality of life, and drug intake in implanted subjects. The study included 30 participants with chronic migraine (100% of participants) and medication overuse headache (85% of participants) who were implanted with an occipital nerve stimulator (ONS) and randomized to one of two arms: (1) “Stimulation On” or (2) “Stimulation Off”. The participants crossed over after 1 month, or when their headaches worsened. The participants were provided with remote controls to modify the stimulation amplitude. Follow-up examinations were conducted at 1, 3, 6, and 12 months after stimulator implantation, during which time the stimulation parameters were adjusted. During this 1-year follow-up period, degree of disability (using the Migraine Disability Assessment [MIDAS]), quality of life (using SF-36) and drug intake (using a participant’s diary) were assessed. A total of 29 participants completed the study. The intensity and/or frequency of headache were significantly lower in the “On” arm of the study compared to the “Off” arm and decreased from baseline to each follow-up visit in all participants with stimulation on. The degree of disability improved during the study as reflected by the median MIDAS score decreasing from 79 at baseline to 10 at 12-month follow-up. With regard to medication usage, triptans and nonsteroidal anti-inflammatory drug use decreased from the baseline (20 and 25.5 doses/month) at each follow-up visit, to 3 and 2 doses/month at 1 year, $P<0.001$). A total of five adverse events occurred: two infections (6.7%) and three lead migrations (10%). The authors concluded that ONS appears to be a safe and effective treatment for carefully selected individuals with CM and MOH. The small number of participants is one of the limitations of this study.

Burns and colleagues (2008) studied 14 individuals with medically intractable chronic cluster headaches (CCH). Participants were implanted with bilateral electrodes in the suboccipital region for ONS. Twelve individuals used the stimulation continuously while 2 used it intermittently. A retrospective assessment of their clinical outcome was obtained. At a median follow-up of 17.5 months (range 4-35 months), 10 of 14 participants reported improvement and 9 of these recommend ONS. Three participants noticed a marked improvement of 90% or better (90%, 90%, and 95%), 3 subjects reported a moderate improvement of 40% or better (40%, 50%, and 60%), and 4 subjects reported a mild improvement of 20-30% (20%, 20%, 25%, and 30%). Improvement occurred within days to weeks for those who responded most and participants consistently reported their attacks returned within hours to days when the device was off. One participant found that ONS helped abort acute attacks. Adverse events of concern were lead migrations and battery depletion. The authors concluded that ONS offers a safe, effective option for some individuals with CCH, however more research is required to evaluate safety and efficacy of this therapy.

Schwedt and colleagues (2007) performed a retrospective analysis of 15 individuals with medically refractory headache treated with occipital nerve stimulation. Pre- and post-implant data regarding headache frequency, severity, disability, depression and post stimulator complications were collected. Ages ranged from 21 to 52 years (mean 39 years). Eight individuals had chronic migraine, 3 chronic cluster, 2 hemicrania continua and 2 had post-traumatic headache. Eight individuals underwent bilateral and 7 had unilateral lead placement. Individuals were measured after 5-42 months (mean 19). All six mean headache measures improved significantly from baseline ($p<0.03$). Headache frequency per 90 days improved by 25 days from a baseline of 89 days; headache severity (0-10) improved 2.4 points from a baseline of 7.1 points; migraine disability assessment (MIDAS) improved 70 points from a baseline of 179 points; Headache Impact Test™ HIT-6 scores improved 11 points from a baseline of 71 points; Beck Depression Inventory (BDI-II)

improved 8 points from a baseline of 20 points; and the mean subjective percent change in pain was 52%. Most individuals (60%) required lead revision within 1 year. One individual required generator revision. Occipital nerve stimulation may be effective in some individuals with intractable headache. The authors determined that further well-designed clinical studies are necessary for individuals with medically refractory headache.

Supraorbital Nerve Stimulation

Researchers have also been exploring the use of supraorbital nerve stimulation as a treatment for CM. Supraorbital involves the neurostimulation of both occipital and supraorbital nerves. Clark and colleagues (2016) evaluated long-term pain reduction in 16 participants (12 female; 4 male) who received dual supraorbital and occipital nerve stimulation as a treatment for CM. Participants were assessed with MIDAS and BDI both preoperatively and postoperatively. Selected predictor variables included subjects with ≥ 50% improvement of pain, disability status, number of years from diagnosis to implantation, and the use of narcotics. Functional outcome variables included net improvement of ranked BDI and MIDAS scores. Multivariate analysis of variance was performed to determine the correlation between the outcome and predictor variables. Follow-up ranged from 5 to 80 months (average 44.5 months). At most recent follow-up, 8 subjects had a positive response (≥ 50% improvement in headache), which was the only predictor of functional outcome (total MIDAS, MIDAS-B, and BDI) (p=0.021). Of note, improvement in functional outcome was only significant during the 3-6 month perioperative period and not throughout long-term follow-up, when most follow up MIDAS and BDI scores were elevated. The authors concluded that while the individuals in their small, observational study, with a positive response to supraorbital nerve stimulation and ONS reported overall improvement in their functional status as reflected by MIDAS and BDI in the perioperative period, this effect waned over the long-term follow-up.

In 2015, Reed and colleagues reported on the results of a small case series which explored the concordant use of occipital and supraorbital neurostimulation therapy for hemiplegic migraine. A total of 4 participants with hemiplegic migraine were treated with concordant combined supraorbital and occipital neurostimulation over periods ranging from 6-92 months. The researchers assessed headache frequency and severity, frequency of hemiplegic episodes, medication usage, functional impairment, and participant satisfaction. The participants reported the average headache frequency decreased by 92% (from 30 to 2.5 headache days/month). The Visual Analog Score decreased by 44% (from 9.5 to 5.3). The frequency of hemiplegic episodes diminished by 96% (from 7.5 to 0.25 hemiplegic episodes/month). The headache medication usage decreased by 96% (from 6 to 0.25 daily medications) and the Migraine Disability Assessment score was reduced by 98% (from 249 to 6). All of the participants reported preferring combined occipital-supraorbital neurostimulation to occipital neurostimulation alone. The authors concluded that concordant combined occipital and supraorbital neurostimulation may provide effective relief for both the pain and motor aura in some individuals with hemiplegic migraine.

Reed and colleagues (2010) investigated the use of combined occipital and supraorbital neurostimulation in 7 subjects with CM. The researchers evaluated responses to two stimulation programs: one that stimulated the occipital leads only and one that stimulated both the occipital and supraorbital leads together. Based on a follow-up period ranging from 1 to 35 months, all of the participants reported a full therapeutic response but only to combined supraorbital-occipital neurostimulation.

While small, preliminary studies investigating the use of supraorbital neurostimulation as a treatment for CM may show some improvement in pain management, additional well-designed studies with larger populations and longer follow-up periods are needed before conclusions regarding the safety and efficacy of this technique can be made.

At this time, no permanently implantable device has been approved or cleared by the U.S. Food and Drug Administration (FDA) for ONS. Clinical trials evaluating the safety and efficacy of ONS for migraine headaches have been conducted for at least two ONS devices: ONSTIM® (Medtronic Neuro) and PRISM® (Boston Scientific Corporation).

Trigeminal Nerve Stimulation

The majority of the peer-reviewed published research exploring the use of surgically implanted (subcutaneous) trigeminal nerve stimulation has focused on craniofacial pain disorders, such as trigeminal neuralgia. Although researchers have explored the use of external trigeminal nerve stimulation for behavioral health conditions such as anxiety, posttraumatic stress disorder and depression, a review of the literature revealed only a single study that investigated implanted trigeminal nerve stimulation for a mental health condition. Gorgulho and colleagues (2019) conducted a clinical trial (NCT02239809) to assess the safety, efficacy, tolerability and placebo effect duration of continuous subcutaneous trigeminal nerve stimulation in individuals with treatment-resistant depression (TRD). The single-center, double-blinded, controlled trial randomized 20 individuals with unipolar TRD to receive implanted trigeminal nerve stimulation or sham stimulation as an adjuvant to medical therapy. At the time of this review, the results of this study had not been published.

Trigeminal Nerve Stimulation for Trigeminal Neuralgia

Trigeminal neuralgia (TN) is a chronic pain condition that affects the trigeminal (5^{th} cranial) nerve, one of the most widely distributed nerves in the head. Treatment options include pharmacologic therapy, surgical interventions (including but not limited to rhizotomy), and complementary approaches such as acupuncture, yoga and biofeedback. Trigeminal nerve stimulation has been explored as a treatment for trigeminal neuralgia. Similar to occipital nerve stimulation and supraorbital nerve stimulation, trigeminal nerve stimulation involves the implantation of a pulse generator and electrodes to deliver mild electrical signals to branches of the trigeminal nerve in order to provide neuromodulation of pain. Although implantation of the electrodes is considered a minimally invasive procedure, it is not without risks. Postoperative complications may include nerve damage, pain, infection, electrode migration, mechanical failure (e.g., disconnection of hardware and failure to provide adequate pain relief) and cosmetic concerns.

William and colleagues (2016) reported the results of a retrospective study evaluating the feasibility of trigeminal and spheno-palatine ganglion (SPG) stimulation for trigeminal neuropathic pain, anesthesia dolorosa, and persistent idiopathic facial pain. A total of 7 subjects received either trigeminal and/or SPG stimulation with or without peripheral nerve stimulation, having failed multiple alternative modalities of treatment. The treatments were tailored to the physical location of pain to safeguard regional coverage with the stimulation. Frameless stereotaxy or fluoroscopy was used to position the SPG and/or trigeminal ganglion stimulator. Trial leads implanted in the pterygopalatine fossa near the SPG were surgically placed using transpterygoid (lateral-medial, infra-zygomatic) approach. The percutaneous Hartel approach was used to implant trial leads in the trigeminal ganglion, all of which resulted in masseter contraction. All participants were initially trialed prior to implantation. Participants who developed clinically significant pain improvement during the trial underwent implantation. Of the 7 participants, 2 did not respond well to the trial and did not undergo implantation; of the 5 participants who underwent implantation, 4 (80 %) reported sustained improvement of facial pain with a mean follow-up of 9.6 months (range, 1–24). The authors concluded that refractory neuropathic facial pain may respond positively to ganglionic forms of stimulation and that implantation of the electrodes using the pterygopalatine fossa via a lateral transpterygoid approach was both safe and effective. The authors also concluded that implantation of an electrode grid overlying Meckel's cave appeared to be a reasonable alternative to the Hartel approach but further investigation is needed to evaluate the usefulness of these approaches for various facial pain conditions. The authors acknowledged limitations of the study included its small size, retrospective design, the lack of additional pain scales and the possible impact of a surgical placebo effect.

Abd-Elsayed and colleagues (2015) reported the results of a study assessing the effectiveness of trigeminal nerve stimulation in a single individual with trigeminal neuralgia resistant to conventional pain management. Pain scores were recorded prior to and following the procedure, and the subject reported complete resolution of her pain. The authors concluded that trigeminal nerve stimulation is both a safe and effective method to treat trigeminal neuralgia, but also conceded that additional research is needed to define its mechanism of action.

Lenchig and colleagues (2012) reported the results of a case study involving trigeminal nerve stimulation as a treatment of posttraumatic trigeminal neuropathic pain in an individual who had failed conservative management. The researchers recorded the participant's subjective assessment of pain and daily function prior to and subsequent to the procedure. Following the procedure, the subject's pain score decreased approximately 50% and the participant reported an improvement in daily function as well as a more positive outlook on her condition. No complications were reported after the procedure and the participant reported no complaints with the device.

In 2004, Johnson and colleagues reported the results of a retrospective case series of 10 individuals who underwent trigeminal nerve stimulation as a treatment of trigeminal neuropathic pain secondary to herpetic infection or facial trauma. The researchers determined long-term treatment results by completing a retrospective review of medical records (1998-2003) and by independent observers interviewing participants using a standard questionnaire. Degree of pain relief, surgical complication rate, preoperative symptom duration, preoperative and postoperative work status, postoperative changes in medication usage, and overall degree of therapy satisfaction were measured. Mean follow-up duration was 26.6 ± 4.7 months. The authors reported that trigeminal nerve stimulation imparted at least 50% pain relief in 70% of subjects with trigeminal neuropathic pain or postherpetic neuralgia. Medication usage decreased in 70% of participants, and 80% of participants indicated that they were mostly or completely satisfied with treatment overall. No treatment failures (< 50% pain relief and a lack of decrease in medication use) were reported in the posttraumatic group, and two failures (50%) occurred in the postherpetic group. The complication rate necessitating reoperation was 30%. The authors concluded that stimulation of the infraorbital or supraorbital branches of the trigeminal nerve is an effective method for relief of trigeminal neuropathic pain following facial trauma or herpetic infection. The authors also conceded that a prospective trial using this novel approach to treat these disorders is warranted.

A Cochrane review on "Neurosurgical Interventions for the Treatment of Classical Trigeminal Neuralgia" (Zakrzewska, 2011) noted that "there is very low quality evidence for the effectiveness of most neurosurgical procedures for trigeminal neuralgia because of the poor quality of the trials. All procedures produced variable pain relief, but many resulted in sensory side effects … Well-designed studies are urgently needed". The review does not specifically address trigeminal nerve stimulation as a treatment of trigeminal neuralgia.

Several nerve stimulation devices to treat pain have received FDA 510(k) clearance; however, none of these devices is intended to treat pain in the craniofacial (trigeminal nerve) region.

Authoritative Recommendations and Guidelines

In 2021 the American Headache Society published a consensus statement on integrating new migraine treatments into clinical practice (Ailani, 2021). This document states, "Neuromodulatory devices can also be considered…" including electrical trigeminal nerve stimulation. However, no additional rationale is provided for this statement, and two supporting citations address non-invasive treatment methods.

The Congress of Neurological Surgeons published guidelines for ONS for the treatment of medically refractory occipital neuralgia (Staudt, 2023). Based on their review of the evidence, the guidelines support the use of ONS as a treatment option for individuals with medically refractory occipital neuralgia. The authors assigned a Level III grade to this recommendation, indicating that the recommendation is based on evidence from case series, case reports, comparative studies with historical controls, and expert opinion, as well as significantly flawed randomized, controlled trials.

Background/Overview

Peripheral (occipital and supraorbital) and cranial (trigeminal) nerve stimulation using an implantable device has been investigated as an approach to treat various chronic pain conditions. Regardless of the specific nerve targeted, the surgical procedure involves the surgical implantation of a small electrical device (a wire-like electrode) adjacent to the selected nerve(s). The electrode delivers rapid electrical pulses near the selected nerve. During the trial stimulation, the electrode is connected to an external device, and if the trial is successful, a small generator is implanted into the subject's body. An electrical current is delivered from the generator to the nerve or nerves using one or several electrodes. The subject is able to control the intensity of the stimulation by turning the device on and off and adjusting stimulation parameters as needed.

Use of an implantable nerve stimulation device may be referred to as occipital, supraorbital or trigeminal nerve stimulation, depending upon the nerves that are being targeted for stimulation.

The implantation of an occipital, supraorbital or trigeminal nerve stimulation device may cause some complications. Lead migration is the most frequent problem, requiring removal and replacement. Power depletion in the pulse generator also needs to be addressed. As with all surgery, the possibility of infection has to be considered.

Definitions

Afferent: A nerve that carries impulses toward the central nervous system (CNS). The opposite of an afferent nerve is an efferent nerve that carries impulses away from the CNS.

Cluster Headaches: Sudden, intensely painful headaches that occur repeatedly in groups or clusters.

Intractable: Having no relief, such as a symptom or a disease that is not relieved by the therapeutic measures.

Migraine: A vascular headache believed to be caused by blood flow changes and certain chemical changes in the brain leading to a cascade of events that include constriction of arteries supplying blood to the brain that result in severe head pain, stomach upset, and visual disturbances.

Nociceptive: The ability of specific portions of the nervous system to sense and transmit painful stimuli.

Peripheral nerves: Nerves that are located beyond the spinal cord or brain.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following codes when describing implantation of an occipital, supraorbital or trigeminal nerve stimulator implantable device, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
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
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing 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
HCPCS	
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
ICD-10 Procedure	
	For the following codes when specified as an occipital, supraorbital or trigeminal nerve stimulator:
00HE0MZ	Insertion of neurostimulator lead into cranial nerve, open approach
00HE3MZ	Insertion of neurostimulator lead into cranial nerve, percutaneous approach
00HE4MZ	Insertion of neurostimulator lead into cranial nerve, percutaneous endoscopic approach
01HY0MZ	Insertion of neurostimulator lead into peripheral nerve, open approach
01HY3MZ	Insertion of neurostimulator lead into peripheral nerve, percutaneous approach
01HY4MZ	Insertion of neurostimulator lead into peripheral nerve, percutaneous endoscopic approach
ICD-10 Diagnosis	
	All diagnoses, including but not limited to, the following:
F33.0-F33.9	Major depressive disorder, recurrent
G43.001-G43.E19	Migraine
G44.001-G44.89	Other headache syndromes
G50.0-G50.9	Disorders of trigeminal nerve
M54.81	Occipital neuralgia
R51.0-R51.9	Headache

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, References, and Index sections. Updated Coding section with 01/01/2024 CPT changes, updated descriptor for 64590.
	09/27/2023	Updated Coding section with 10/01/2023 ICD-10-CM changes; added G43.E19 to end of range.
Reviewed	11/10/2022	MPTAC review. Updated References and History sections.
Reviewed	11/11/2021	MPTAC review. Updated Rationale and References sections. Updated Coding section with 01/01/2022 CPT descriptor changes for 64568, 64575.
Reviewed	11/05/2020	MPTAC review. Updated Rationale, Coding and References section.
Revised	08/13/2020	MPTAC review. Title changed to “Implantation of Occipital, Supraorbital and Trigeminal Nerve Stimulation Devices (and Related Procedures)”. Added trigeminal nerve stimulation and related procedures to the document. Reworded position statements for occipital and supraorbital nerve stimulation to clarify document addresses implanted occipital and supraorbital nerve stimulation devices. Updated review date, Description/Scope, Rationale, Background/Overview, Definitions, References, Index and History sections. Updated Coding section to add codes 61885, 64568, 64569, C1767, C1778; also added 10/01/2020 ICD-10-CM changes, R51.0-R51.9 replacing R51.
Reviewed	11/07/2019	MPTAC review. Updated review date, References and History sections.
Reviewed	01/24/2019	MPTAC review. Updated review date, References and History sections.
Revised	01/25/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Title changed to “Occipital Nerve and Supraorbital Nerve Stimulation”. Added new position statement which states “Supraorbital nerve stimulation is considered investigational and not medically necessary for all indications”. Updated review date, Description/Scope, Rationale, Coding, References and Index sections.
Reviewed	05/04/2017	MPTAC review. Updated review date, Rationale and References sections.
Reviewed	05/05/2016	MPTAC review. Updated review date, Rationale and References sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated review date, Rationale and References sections.
Reviewed	05/15/2014	MPTAC review. Updated review date, Rationale, Coding and References sections.
Reviewed	05/09/2013	MPTAC review. Updated review date, Rationale and References sections.
Reviewed	05/10/2012	MPTAC review. Updated review date, References and History sections.
Reviewed	05/19/2011	MPTAC review. Updated review date, References and History sections.
Reviewed	05/13/2010	MPTAC review. Updated review date, References and History sections.
New	05/21/2009	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.