MEDICAL POLICY	Occipital Nerve Stimulation and Ablation (All Lines of Business Except Medicare)	
Effective Date: 4/1/2021  4/1/2021 Medical Officer Date	Section: SUR	Policy No: 292
	Technology Assessment Committee Approved Date: 8/06; 9/08; 10/10; 8/11 Medical Policy Committee Approved Date: 1/13; 3/14; 8/15; 5/16; 7/17; 1/18; 2/18; 12/18; 11/19; 1/2021	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All Lines of Business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Note: For Medicare members, please see Medical Policy: "Peripheral Nerve Stimulation for Chronic Pain (Medicare Only)."

I. Electrical stimulation of the occipital nerve is considered **investigational and is not covered** for all indications, including, but not limited to, occipital neuralgia, cluster headaches or refractory migraine headache.

II. Ablation of the occipital nerve (e.g. cryoablation, pulsed radiofrequency ablation) is considered **investigational and is not covered** for all indications, including but not limited to occipital neuralgia, cluster headaches or refractory migraine headache.

Link to Policy Summary

CPT/HCPCS CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex

	cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
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
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

Prior Authorization Required Note: When billed for occipital nerve ablation, the following two codes are considered investigational and are not covered.	
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
No Prior Authorization Required	
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming

DESCRIPTION

Cluster Headache

According to ECRI, "cluster headaches are a primary neurovascular disorder that patients experience as severe to very sever, one-sided head pain. Chronic CHs typically occur every other day, daily, or even several times daily with pain lasting from 15 minutes to a few hours."[1]

Migraine Headache

Migraine headache is defined as recurring headache attacks lasting 4 to 72 hours. "Typical characteristics of the headache are unilateral location, pulsating quality, moderate-to-severe intensity, aggravated by routine physical activity, associated with nausea, and/or photophobia and phonophobia." Migraines can also include an aura or perceptual disturbance. Common treatments of migraines include nonsteroidal anti-inflammatory drugs (NSAIDs), steroids, and triptans (e.g., sumatriptan). Preventative therapies are also available, including calcium channel blockers and corticosteroids.

Occipital Neuralgia

Occipital neuralgia is a rare neurological disorder characterized by piercing, throbbing, or electric-shock-like pain in the upper neck, back of the head, and behind the ears, usually on one side of the head. Commonly, the cause of occipital neuralgia is unknown; however, it can occur due to irritation or injury to the occipital nerve. Therapies for occipital neuralgia may include pain medications, anesthetic injection, and steroids to reduce inflammation and block the transmission of pain signals.

Ablation of the Occipital Nerve

Ablative procedures (e.g. cryoablation, radiofrequency ablation, rhizotomy) are performed in the attempt to denervate the occipital nerve (greater or lesser), upper cervical nerve (eg, second cervical nerve, also known as C2), supraorbital, supratrochlear or sphenopalatine ganglion. The proposed goal of denervation is to disrupt pain signals sent from the nerves to the brain without causing excessive sensory loss, motor dysfunction or other complications.

Occipital Nerve Stimulation (ONS)

ONS involves the implantation of subcutaneous electrodes at the base of the skull over the greater, lesser, or third occipital nerves. The electrodes are connected to leads which are tunneled together in a caudal direction to an impulse generator implanted in the chest wall, low back, buttocks, or abdomen. The generators can be controlled by the physician or patient and can provide continuous or intermittent stimulation. Additionally, the generators can be non-rechargeable with a 2 to 5 year lifespan or rechargeable.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of occipital nerve stimulation as a treatment for refractory migraine headache or occipital neuralgia. Below is a summary of the available evidence identified through November 2020.

The U.S. Food and Drug Administration has not approved occipital neurostimulation devices as a treatment of any condition, including refractory migraine headache or occipital neuralgia. Therefore, the use of occipital neurostimulation for these indications, like described in the clinical research studies below, is considered an off-label use of the device.

Occipital Nerve Stimulation

Systematic Reviews

- In 2020, Hayes conducted an evidence review evaluating the safety and efficacy of occipital nerve stimulation (ONS) for the treatment of chronic cluster headaches (CH).[2] In total, 1 retrospective comparative cohort study, 4 prospective or retrospective pretest/posttest studies, and 2 prospective case series were included for review. Sample sizes ranged from 15 to 67 patients and follow-up ranged from 3 months to 6.1 years. Outcomes of interest included cluster headache frequency, intensity, medication use, functional improvement, quality of life, and complications.

  Across studies, patients achieved a clinically meaningful ≥ 50% decrease in CH attacks from baseline in 41% to 90% of those treated. Reduction in intensity of pain during a CH attack from

baseline varied widely (range, 11%-96%) across studies. One comparative study found that deep brain stimulation (DBS) was more effective than ONS since a significantly greater number of patients achieved a ≥ 50% decrease in CH attacks from baseline in the DBS group than in the ONS group (100% versus 41%).

Despite positive results, Hayes determined that the evidence evaluated was small in size and "very low" in quality. The 7 available studies involving fewer than 250 patients were small and only 1 study involved a control group. The controlled study found ONS to be less effective than DBS. Although the 6 uncontrolled studies found that ONS treatment was associated with clinically meaningful reductions in headache frequency (≥ 50%) compared with pretreatment in 41% to 90% of patients, it is difficult to determine the reliability of these findings since they may have been at least partly due to placebo effects and spontaneous improvements. Investigators ultimately concluded that evidence was insufficient ("D2" rating) and that additional larger, well-designed studies are needed to determine whether ONS is an effective treatment for refractory, chronic CH.

- In 2020, Hayes conducted an evidence review evaluating the safety and efficacy of occipital nerve stimulation (ONS) for the treatment of chronic migraine headaches (HA).[3] In total, 8 studies including 4 RCTs were included for review. Samples sizes ranged from 8 to 157 patients and follow-up ranged from 3 months to 9.4 years. Outcomes of interest included headache frequency, pain intensity, response-rate, disability, affective measures, patient satisfaction, migraine/pain medication use and complications.

  Across 7 studies, ONS treatment appeared to consistently result in improvements in HA frequency despite variations in HA frequency definitions and follow-up times; however, the percentages of patients with a treatment response to ONS (i.e., reduction in HA frequency) varied widely across the studies (from 9% to 88.6%). In addition, the clinical significance of the decreases was not explored in detail in any of the studies. An overall positive effect of ONS treatment on HA intensity was reported despite the lack of statistical significance in 1 RCT, the lack of statistical reporting in another RCT, and variations in HA intensity definitions and follow-up times. However, the percentages of patients experiencing a treatment response to ONS (e.g., reduction in HA intensity) varied across the studies from 17.1% to 66% of patients. Results across 5 studies indicated that ONS treatment may potentially improve migraine-related disability, but results were inconsistent. Some quality of life improvements were reported, but due to some mixed results and the small number of studies evaluating this outcome, the impact of ONS treatment on QOL is inconclusive.

  Hayes ultimately assigned a "C" rating (potential, but unproven benefit) concluding that ONS appears to have a positive but variable treatment effect on HA outcomes in selected patients, particularly in reductions of frequency and intensity, albeit with a risk of complications that may require additional surgery. Nonetheless, the overall quality of evidence was assessed as "low" due to inconsistent study designs and lack of uniform patient selection criteria.

- In 2019, ECRI conducted an evidence review of occipital nerve stimulation (ONS) for the treatment of medically refractory chronic cluster headaches. Searching the literature through July 2019, investigators reviewed full text of the systematic review (5 case series; n =175) and the abstract of the case series on 226 patients.[1] The systematic review evaluated the ONS treatment for patients with medically refractory chronic CH, reporting the percentage of patients who experienced at least 50% improvement in headache frequency and/or intensity. One prospective case series (n=51) not included in the systematic review reported the percentage of patients who experienced at least 50% improvement in headache frequency and/or intensity. Both studies reported efficacy ranging from 50%-89% among patients undergoing ONS. ECRI concluded that evidence was "inconclusive" to support the use of ONS for the treatment of medically refractory chronic cluster headaches. Limitations among reviewed studies included small sample size, and lack of controls, randomization and blinding.

- In 2017, Cadalso et al. conducted a systematic review and meta-analysis to evaluate the efficacy of electrical stimulation of the occipital nerve (ONS) in intractable primary headache disorders.[4] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contact, if necessary, for additional information or data. The primary outcomes of interest included headache frequency and headache intensity.

  Following a systematic review of the evidence, the authors identified 4 randomized controlled trials (RCTs), 1 follow-up study, and 19 case series as eligible for inclusion. "The quality of the evidence was low, with all four RCTs assessed as having a high risk of bias and small sample size."[4] After the pooling of data from 3 RCTs, the results indicated patients receiving ONS therapy had a significant reduction of 3 headache days per month (p=0.004) and in the Migraine Disability Assessment score (p<0.001) when compared to sham therapy. However, there were no statistically significant differences for reduction in pain intensity (p=0.060) or in the number of responders (p=0.229).

  The methodological strengths of this systematic review included the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers, contacting authors of selected studies for additional information or data, and assessment of heterogeneity and publication bias. Limitations are present in the small number of studies included in the meta-analysis and the high risk of bias of the selected studies. Ultimately, the authors concluded, "ONS may be effective when compared to sham therapy, but the small number of RCTs and the heterogeneity of outcomes suggest further research in this field is needed."[4]

<u>Randomized Controlled Trials (RCTs)</u>

The evidence review identified two RCTs not included in the systematic review described above.[5,6] Although both studies conclude occipital nerve stimulation (ONS) is efficacious for the treatment of migraines, the validity of these conclusions is significantly limited. Both studies included very small sample sizes of 110 and 20 patients, respectively. In addition, both studies had short follow-up periods of 1 month and 12 months. Finally, one study which evaluated complications following ONS therapy

reported 15 of 20 patients (75%) experienced a treatment-associated adverse event. Due to these methodological limitations and poor safety profile, the safety and efficacy of ONS for migraine headaches is not supported.

Ablation of the Occipital Nerve

In 2018, Grandhi and colleagues published a systematic review investigating the use of radiofrequency ablation (RFA) and pulsed radiofrequency ablation (PRFA) for the management of cervicogenic headache (CHA).[7] Independent investigators systematically searched the literature through February 2017, identified eligible studies, assessed study quality and extracted data. In total, 10 studies met inclusion for review (n = 3 randomized controlled trials, 3 prospective trials, and 4 retrospective trials). While numerous case reports demonstrated benefit, investigators concluded that there was a lack of high-quality RCTs and/or strong non-RCTs to support the use of RFA and PRFA in the management of CHA. Limitations included studies' small sample sizes, lack of long-term follow-up, heterogenous treatment parameters, and lack of randomized comparator groups.

CLINICAL PRACTICE GUIDELINES

Occipital Nerve Stimulation

Congress of Neurological Surgeons

The 2015 evidence-based Congress of Neurological Surgeons guideline for occipital nerve stimulation in patients with medically refractory occipital neuralgia stated, "data from a recent systematic review of the literature supports the use of occipital nerve stimulation (ONS) as a treatment option for patients with medically refractory occipital neuralgia (ON) (Level III recommendation)."[8] However, the validity of this recommendation is questionable as it is a level 3 recommendation based on poor quality case series and expert opinion.

National Institute for Health and Care Excellence (NICE)

The 2013 evidence-based NICE guideline for occipital nerve stimulation for intractable chronic migraine stated, "(t)he evidence on occipital nerve stimulation (ONS) for intractable chronic migraine shows some efficacy in the short term but there is very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."[9]

Ablation of the Occipital Nerve

No clinical practice guidelines addressing ablation of the occipital nerve were identified.

POLICY SUMMARY

There is insufficient evidence to support the safety and efficacy of occipital nerve stimulation (ONS) for refractory migraine headaches or occipital neuralgia. Additionally, the U.S. FDA has not approved any occipital neurostimulation devices for these indications. Although the 2015 guideline from the Congress of Neurological Surgeons recommended the use of ONS, the reliability of this recommendation is poor as it is based on case series and expert opinion. FDA approval and publication of high-quality studies are required to establish the safety and medical necessity of occipital nerve stimulation for the treatment of migraine headaches and occipital neuralgia. Evidence addressing ablation of the occipital nerve is also limited, with no demonstrated clinical utility reported in high-quality studies.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHP and PHA Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food and Drug Administration (FDA)

Currently, the FDA has not approved any occipital neurostimulation devices for the treatment of refractory migraine headache or occipital neuralgia; therefore, this would be considered an off-label use of the device. The following devices were used in the research studies evaluating occipital nerve stimulation for refractory migraine headache or occipital neuralgia.

Device Name & Manufacturer	Indications for Use
Synergy Dual-Program Neurostimulators by Medtronic[10]	The Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulators are part of dual-program systems for spinal cord stimulation. The systems are indicated as an aid in the management of chronic, intractable pain of the trunk or limbs. Patients should be carefully selected to assure that their pain is of physiological origin. Also, patients must be appropriate candidates for surgery.

Genesis Neurostimulation (IPG) System by Advanced Neuromodulation Systems (ANS), Inc.[11]	ANS Genesis Neurostimulation (IPG) System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back and leg pain.

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY CROSS REFERENCES

- Back: Ablative Procedures to Treat Back and Neck Pain (All LOB Except Medicare), SUR130
- Back: Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (Medicare Only), SUR125

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11. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: Genesis Neurostimulation (IPG) System. https://www.accessdata.fda.gov/cdrh_docs/pdf/P010032b.pdf. Published 2001. Accessed 11/23/2020.