APPENDIX to Occipital Nerve Stimulation Policy

Prior Authorization Requirements

This service (or procedure) is considered **investigational** in all instances. If you would like to submit additional information please forward to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Implanted peripheral nerve stimulators have been used for treatment of refractory pain for many years but only recently proposed for management of craniofacial pain. Occipital, supraorbital, and infraorbital stimulation have been reported in the literature.

There are four types of headache: vascular, muscle contraction (tension), traction, and inflammatory. Primary chronic headache is defined as headache occurring more than 15 days of the month for at least three months. An estimated 45 million Americans experience chronic headaches. For at least half of these people, the problem is severe and sometimes disabling.

Migraine is the most common type of vascular headache. Migraine headaches are usually characterized by severe pain on one or both sides of the head, an upset stomach, and, at times, disturbed vision. One- year prevalence of migraine ranges from 6% to 15% in adult men and from 14% to 35% in adult women. Migraine headaches may last a day or more and can strike as often as several times a week or as rarely as once every few years. Drug therapy for migraine is often combined with biofeedback and relaxation training.

Hemicrania continua, also a vascular headache, causes moderate pain with occasional severe pain on only one side of the head. At least one of the following symptoms must also occur; conjunctival injection and/or lacrimation, nasal congestion and/or rhinorrhea, or ptosis and/or miosis. Headache occurs daily and is continuous with no pain-free periods. Hemicrania continua occurs mainly in woman, and its true prevalence is not known.

Cluster headache is a vascular headache that occurs in cyclical patterns or clusters of severe or very severe unilateral orbital or supraorbital and/or temporal pain. The headache is accompanied by at least one of the following autonomic symptoms: ptosis, conjunctival injection, lacrimation, rhinorrhea, and, less commonly, facial blushing, swelling, or sweating. Bouts of one headache every other day to eight attacks per day may last from weeks to months, usually followed by remission periods when the headache attacks stop completely. The pattern varies from one person to another, but most people have one or two cluster periods a year. During remission, no headaches occur for months, and sometimes even years. The intense pain is caused by the dilation of blood vessels, which creates pressure on the trigeminal nerve. While this process is the immediate cause of the pain, the etiology is not fully understood. It is more common in men than in woman. One-year prevalence is estimated to be 0.5 to 1.0 per 1,000.

Currently, the United States Food and Drug Administration (FDA) have not cleared any occipital nerve stimulation (ONS) device for treatment of headache. The Synergy IPG implanted stimulator device from Medtronic, Inc., (Minneapolis, MN) received marketing clearance in 1999 for management of chronic, intractable pain of the trunk or limbs, and off-label use for headache is described in the literature.

Evidence of efficacy for ONS for treatment of chronic headache is limited to reports of small case series with short follow-up.

Trentman et al., (2009) reported outcome measures at one year post-implant in nine patients who participated in a feasibility trial of the Bion microstimulator. One patient stopped using the device before one year because of the time required recharging the device. At one year, seven of the eight remaining patients had fair or better results in terms of reduction of disability with five having greater than 90% reduction in disability.

Schwedt and colleagues (2007) published a retrospective analysis of pre- and post-implant data from 15 patients with chronic, intractable headache implanted with the Synergy implantable pulse generator. Eight patients had chronic migraine, three chronic cluster, two hemicrania continua, and two post-traumatic headaches. Eight patients had bilateral and seven had unilateral lead placement. Nine patients reported at least a 50% reduction in headache pain, and none reported worsening of pain. The mean subjective percent change in pain was 52%. Sixty percent of patients required lead revision within one year. The authors concluded ONS may be effective in some patients with intractable headache. In a separate report, the same authors describe a retrospective review of the patients in the study reported above to determine if response to occipital nerve block (ONB) predicts response to ONS (Schwedt et al., 2007). Thirteen patients in the study had ONB; 10 of them were responders (50% or more reduction in frequency or severity). Ten of 13 who had ONB had significant relief of pain lasting at least 24 hours, and three were ONB non-responders. Of the three ONB non-responders, two were ONS responders. Of the two patients who did not have ONB prior to ONS, one was an ONS responder and one was an ONS non-responder. The authors concluded ONB may not be predictive of the therapeutic effect of ONS.

Burns et al., (2009) reported on 14 patients with cluster headache implanted with bilateral electrodes. At a median follow-up of 17.5 months (range four to 35 months), 10 of 14 patients reported improvement. Three reported improvement of 90% or better; three reported moderate

improvement (30% to 60%), and four reported mild improvement (20% to 30%). Four patients required new electrode leads. A wide range of stimulation was used. Six patients required battery replacement. Muscle recruitment, neck stiffness, skin discomfort, superficial infections, and painful overstimulation were reported in a crossover study, also by Burns and colleagues (2008); six patients with hemicrania continua received continuous unilateral ONS. Pain on a 10-point scale was recorded hourly in patient diaries and the Migraine Disability Assessment Scale was administered at each follow-up visit. Four of six patients reported substantial improvement (80% to 95%), one reported a 30% improvement, and one reported pain was worse by 20%. Adverse events were mild and associated with transient overstimulation.

Combined occipital and supraorbital neurostimulation was evaluated in seven patients with chronic migraine by Reed and colleagues (2009). Responses to two stimulation programs were evaluated: one that stimulated only the occipital leads and one that stimulated both the occipital and supraorbital leads together. With follow-up ranging from one to 35 months, all patients reported a full therapeutic response but only to combined supraorbital-occipital neurostimulation.

In summary, randomized controlled trials (to account for potential placebo effect) with greater numbers of patients and longer follow-up are needed. In addition, these trials must compare outcomes of ONS with outcomes of other possible alternative treatments. The available evidence, from small uncontrolled trials, is insufficient to permit conclusions concerning the impact of ONS on health outcomes. In addition, no implanted ONS devices have received FDA approval. Therefore, ONS is considered investigational.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical

Type	Number	Description
	61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical
	61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
	61864	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
	61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
	61868	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
	61870	Craniectomy for implantation of neurostimulator electrodes, cerebellar; cortical
	61875	Craniectomy for implantation of neurostimulator electrodes, cerebellar; subcortical
	61880	Revision or removal of intracranial neurostimulator electrodes
	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
	61888	Revision or removal of cranial neurostimulator pulse generator or receiver

Type	Number	Description
	64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve
	64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
	64573	Incision for implantation of neurostimulator electrodes; cranial nerve
	64575	Incision for implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
	64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
	95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and 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, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
	95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
	95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

Type	Number	Description
	95973	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
	95974	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
	95975	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
	95978	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour
	95979	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
HCPC	C1767	Generator, neurostimulator (implantable), nonrechargeable
	C1778	Lead, neurostimulator (implantable)

Type	Number	Description
	C1787	Patient programmer, neurostimulator
	C1816	Receiver and/or transmitter, neurostimulator (implantable)
	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
	C1897	Lead, neurostimulator test kit (implantable)
	L8680	Implantable neurostimulator electrode (with any number of contact points), 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, nonrechargeable, includes extension
	L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
	L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only
ICD9 Procedure	01.20	Cranial implantation or replacement of neurostimulator pulse generator
	02.93	Implantation or replacement of intracranial neurostimulator lead(s)
	04.92	Implantation or replacement of peripheral neurostimulator lead(s)
ICD9 Diagnosis	All Diagnoses	

Type	Number	Description
Place of Service	All Places of Service	

Tables

N/A

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Deep Brain Stimulation
- Spinal Cord Stimulation
- Vagus Nerve Stimulation
- Electrical Stimulation for Pain
- Gastric Electrical Stimulation
- Neuromuscular and Funtional Electric Stimulation
- Sacral Nerve Neuromodulation/Stimulation
- Urinary Incontinence Outpatient Treatment

Key / Related Searchable Words

N/A

References

- Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.125 (February 2010).
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- Burns B, Watkins L, Goadsby P. Treatment of intractable chronic cluster headache by occipital nerve stimulation in 14 patients. Neurology 2009; 72(4):341-5.

- Reed KL, Black SB, Bant CJ 2nd et al. Combined occipital and supraorbital neurostimulation for the treatment of chronic migraine headaches: initial experience. Cephalalgia 2009 Sep 3 [Epub ahead of print].
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- Schwedt TJ, Dodick DW, Trentman TL et al. Response to occipital nerve block is not useful in predicting efficacy of occipital nerve stimulation. Cephalalgia 2007; 27(3):271-4.
- Trentman TL, Rosenfeld DM, Vargas BB et al. Greater occipital nerve stimulation via the Bion Microstimulatro; implantation technique and stimulation parameters Clinical Trial: NCT00205894. Pain Physician 2009; 12(3):621-8.

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
1/7/2011	BCBSA Medical Policy adoption	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy

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