

<b>7.01.125</b>	<b>Occipital Nerve Stimulation</b>		
<b>Original Policy Date:</b>	January 7, 2011	<b>Effective Date:</b>	June 1, 2019
<b>Section:</b>	7.0 Surgery	<b>Page:</b>	Page 1 of 11

## Policy Statement

Occipital nerve stimulation is considered **investigational** for all indications.

## Policy Guidelines

### Coding

There is no specific CPT code for occipital nerve stimulation. The following CPT codes may be used:

- **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
- **64568:** Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
- **64569:** Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
- **64570:** Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
- **64999:** Unlisted procedure, nervous system

## Description

Occipital nerve stimulation delivers a small electrical charge to the occipital nerve intended to prevent migraines and other headaches in patients who have not responded to medications. The device consists of a subcutaneously implanted pulse generator (in the chest wall or abdomen) attached to extension leads that are tunneled to join electrodes placed across one or both occipital nerves at the base of the skull. Continuous or intermittent stimulation may be used.

## Related Policies

- Spinal Cord and Dorsal Root Ganglion Stimulation
- Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

## 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]) prohibits 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.

## **Regulatory Status**

The U.S. Food and Drug Administration has not cleared or approved any occipital nerve stimulation device for treatment of headache. In 1999, the Synergy™ IPG device (Medtronic), an implantable pulse generator, was approved by the Food and Drug Administration through the premarket approval process for management of chronic, intractable pain of the trunk or limbs, and off-label use for headache is described in the literature. The Genesis™ Neuromodulation System (St. Jude Medical) was approved by the Food and Drug Administration for spinal cord stimulation and the Eon™ stimulator has received CE mark approval in Europe for the treatment of chronic migraines.

## **Rationale**

### **Background**

#### **Headache**

There are 4 types of headache: vascular, muscle contraction (tension), traction, and inflammatory. Primary (not the result of another condition) chronic headache is defined as headache occurring more than 15 days of the month for at least 3 consecutive months. An estimated 45 million Americans experience chronic headaches. For at least half of these people, the problem is severe and sometimes disabling. Herein, we only discuss types of vascular headache, including migraine, hemicrania continua, and cluster.

#### **Migraine**

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.

#### **Treatment**

Drug therapy for migraine is often combined with biofeedback and relaxation training. Sumatriptan and other triptans are commonly used for relief of symptoms. Drugs used to prevent migraine include amitriptyline, propranolol and other  $\beta$ -blockers, topiramate and other antiepileptic drugs, and verapamil.

#### **Hemicrania Continua**

Hemicrania continua causes moderate and occasionally 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 women, and its true prevalence is not known.

#### **Treatment**

Indomethacin usually provides rapid relief of symptoms. Other nonsteroidal anti-inflammatory drugs, including ibuprofen, celecoxib, and naproxen, can provide some relief of symptoms. Amitriptyline and other tricyclic antidepressants are effective in some patients.

#### **Cluster Headache**

Cluster headache 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 1 headache every other day up to 8 attacks per day may last from weeks to months, usually followed by remission periods when the headache attacks stop completely. The pattern varies by person, but most people have 1 or 2 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 in 1000.

### **Treatment**

Management of cluster headache consists of abortive and preventive treatment. Abortive treatments include subcutaneous injection of sumatriptan, topical anesthetics sprayed into the nasal cavity, and strong coffee. Some patients respond to rapidly inhaled pure oxygen. A variety of other pharmacologic and behavioral methods of aborting and preventing attacks have been reported with wide variation in patient response.

### **Peripheral Nerve Stimulators**

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

### **Literature Review**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

### **Migraine Headache**

#### **Clinical Context and Test Purpose**

The purpose of occipital nerve stimulation in patients who have migraines is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does occipital nerve stimulation improve the net health outcome in patients who have migraines?

The following PICOs were used to select literature to inform this review.

#### **Patients**

The relevant population of interest are patients with migraine headache.

#### **Intervention**

The therapy being considered is occipital nerve stimulation.

Occipital nerve stimulation delivers a small electrical charge to the occipital nerve intended to prevent migraines and other headaches in patients who have not responded to medications.

The device consists of a subcutaneously implanted pulse generator (in the chest wall or abdomen) attached to extension leads that are tunneled to join electrodes placed across one or both occipital nerves at the base of the skull. Continuous or intermittent stimulation may be used.

### Comparators

The following therapies are currently being used to make decisions about occipital nerve stimulation.

Comparators of interest include medication and self-management (e.g., relaxation, exercise),

### Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Two systematic reviews of the literature on occipital nerve stimulation (ONS) have been published, both including RCTs and observational studies. The review by Chen et al (2015) identified 5 RCTs and 7 case series with at least 10 patients.<sup>1</sup> Three of the RCTs were industry-sponsored, multicenter, parallel-group trials and two were single-center crossover trials. All five included a sham control group and one also included a medication management group. Risk of bias was judged to be high or unclear for all trials. Meta-analyses were performed on 2 outcomes. A pooled analysis of 2 trials did not find a significant difference in response rates between active and sham stimulation (relative risk [RR], 2.07; 95% confidence interval [CI], 0.50 to 8.55;  $p=0.31$ ) and a pooled analysis of 3 trials showed a significantly greater reduction in the number of days with prolonged moderate-to-severe headache (mean difference, 2.59; 95% CI, 0.91 to 4.27;  $p=0.003$ ).

In their systematic review, Yang et al (2016)<sup>2</sup> identified the same 5 RCTs as Chen. The Yang review only included studies conducted with patients who had migraines for at least 6 months in duration who did not respond to oral medications. In addition to the RCTs, 5 case series met the inclusion criteria. Yang did not pool study findings. The definition of response rate varied across studies and could include frequency and/or severity of headaches. Response rates in 3 case series with self-reported efficacy were 100% in each, and response rates in the other 2 series were 50% and 89%, respectively. Complication rates in the series ranged from 40% to 100%. Reviewers noted that the case series were subject to biases (e.g., inability to control for the placebo effect), that RCT evidence was limited, and that complication rates were high. The most common complications were lead migration (21% of patients) and infection (7% of patients).

The 2 parallel-group RCTs published as full-text journal articles are detailed next. The Occipital Nerve Stimulation for the Treatment of Intractable Chronic Migraine Headache trial, was a multicenter, randomized feasibility study of ONS for treatment of intractable chronic migraine headache refractory to preventive medical management.<sup>3</sup> The trial, reported by Saper et al (2011), evaluated study design and had no primary end point. One hundred ten patients were enrolled, and patients who had a positive response to a short-acting occipital nerve block were randomized as follows: 33 to adjustable stimulation, 17 to preset stimulation of 1 min/d, and 17 to medical management. At the 3-month evaluation, the response rate (percentage of patients who achieved  $\geq 50\%$  reduction in number of headache days per month or a  $\geq 3$ -point reduction in average overall pain intensity vs baseline) was 39% in the adjustable stimulation group, 6% in the preset stimulation group, and 0% in the medical management group. Twelve (24%) of 51 subjects who had successful ONS device implantation experienced lead migration and 3 (6%) of the 51 subjects were hospitalized for adverse events (infection, lead migration, nausea). Trial limitations included a short observation period and ineffective blinding of subjects and investigators to treatment groups.

An industry-sponsored, double-blind trial, regulated by the U.S. Food and Drug Administration and reported by Silberstein et al (2012), randomized 157 patients with chronic migraine

refractory to preventive medical management in a 2:1 ratio to active or sham stimulation.<sup>4</sup> Intention-to-treat (ITT) analysis revealed no significant differences between groups in the percentage of patients who achieved 50% or greater reduction in visual analog scale scores for pain at 12 weeks (active, 17.1%; control, 13.5%). More patients in the ONS group had fewer days with headache, less migraine-related disability, and greater pain relief, although benefits were modest. The most common adverse event was persistent implant site pain. Results from the 52-week open-label extension of this trial were published in 2015.<sup>5</sup> Results were reported for the ITT population and for the 125 patients who met selection criteria for intractable chronic migraine. Twenty-four patients were excluded from analysis due to explantation of the ONS system (n=18) or loss to follow-up. Mean headache days at baseline were 21.6 for the ITT population and 24.2 for the intractable chronic migraine group. In the ITT population, headache days were reduced by 6.7 days, and a reduction of 50% or more in the number of headache days and/or pain intensity was observed in 47.8% of this group. Seventy percent of patients experienced at least 1 of 183 device-related adverse events, of which 8.6% of events required hospitalization and 40.7% of events required surgical intervention. Eighteen percent of patients had persistent pain and/or numbness with the device.

### Section Summary: Migraine Headache

Two systematic reviews (2015, 2016) each identified 5 sham-controlled randomized trials. One of the systematic reviews also identified 5 case series. Findings from pooled analyses of RCTs were mixed. For example, compared with sham stimulation, response rates (i.e.,  $\geq 50\%$  reduction in VAS score) for ONS did not differ significantly, but the number of days with prolonged moderate-to-severe headache was reduced. ONS was also associated with a substantial number of minor and serious adverse events.

### Non-Migraine Headaches

#### Clinical Context and Test Purpose

The purpose of occipital nerve stimulation in patients who have non-migraine headache is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does occipital nerve stimulation improve the net health outcome in patients who have non-migraine headache?

The following PICOs were used to select literature to inform this review.

#### Patients

The relevant population of interest is patients with non-migraine headache.

#### Intervention

The therapy being considered is occipital nerve stimulation.

Occipital nerve stimulation delivers a small electrical charge to the occipital nerve intended to prevent migraines and other headaches in patients who have not responded to medications. The device consists of a subcutaneously implanted pulse generator (in the chest wall or abdomen) attached to extension leads that are tunneled to join electrodes placed across one or both occipital nerves at the base of the skull. Continuous or intermittent stimulation may be used.

#### Comparators

The following therapies are currently being used to make decisions about occipital nerve stimulation.

Comparators of interest include medication and self-management (e.g., relaxation, exercise), and self-management.

## Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

## Hemicrania Continua

The evidence evaluating the use of ONS for hemicrania continua consists of a small crossover study by Burns et al (2008) who reported on the efficacy of continuous unilateral ONS in 6 patients.<sup>6</sup> Pain on a 10-point scale was recorded hourly in patient diaries, and the Migraine Disability Assessment was administered at each follow-up visit. Four of 6 patients reported substantially less pain (range, 80%-95% less), one reported 30% less pain, and one reported 20% worse pain. Adverse events were mild and associated with transient overstimulation.

## Cluster Headache

Several case series assessing cluster headache were identified, with sample sizes ranging from 10 to 67 patients.<sup>7-12</sup> Fontaine et al (2017) published a prospective case series of 67 patients with chronic cluster headache.<sup>10</sup> Data were taken from a French ONS database on treatment of refractory headache disorders. Sixty-seven patients with chronic cluster headache were included in the database; data were available for 52 (78%) patients at 3 months and 44 (66%) patients at 12 months. The primary outcome was a composite score that incorporated patient's global impression of change, reduction in the frequency of headache attacks, and changes in prophylactic medications. For patients with available data, at 3 months, 34 (65.4%) of 52 were considered to be excellent responders, 9 (17.3%) of 52 were mild responders, and 9 (17.3%) of 52 were nonresponders. At 12 months, 22 (48%) of 44 were excellent responders, 10 (21.7%) of 44 were mild responders, and 15 (32.6%) of 44 were nonresponders. The series had a large amount of missing data at follow-up.

Leone et al (2017) published a case series on use of ONS in 35 patients with chronic cluster headache.<sup>11</sup> This series had the longest follow-up (median, 6.1 years; range, 1.6-10.7 years). Selection criteria included daily or almost daily cluster headache attacks in the past year and resistance of prophylactic drugs. Twenty (66.7%) of the 30 patients in the per protocol analysis had 50% or more reduction in number of headaches per day and were considered responders. In 12 (40%) patients, improvement was considered stable (i.e.,  $\leq 3$  headache attacks per month).

Limitations of the series reporting on cluster headaches included lack of blinding and comparison groups.

## Headache Associated with Chiari Malformation

Vadivelu et al (2012) reported on a series of 22 patients with Chiari malformation and persistent occipital headaches.<sup>13</sup> Of the 22, 15 (68%) had a successful occipital neurostimulator trial and underwent permanent implantation. At a mean follow-up of 18.9 months (range, 6-51 months), 13 (87%) of the 15 patients reported pain relief greater than 50%. Forty percent of patients reported device-related complications requiring additional surgery (lead migration, uncomfortable position of generator, wound infection) during follow-up.

## Occipital Neuralgia

A systematic review by Sweet et al (2015) identified 9 small case series (<15 patients each) assessing the efficacy of ONS for treating medically refractory occipital neuralgia.<sup>14</sup> Reviewers did not pool study findings. Conclusions cannot be drawn on the impact of ONS on occipital neuralgia due to the lack of RCTs or other controlled studies.

## Section Summary: Non-Migraine Headaches

The evidence on ONS for treatment of non-migraine headaches consists of case series; no RCTs or nonrandomized comparative studies were identified. Many of the case series were small; series with over 25 patients were available only for treatment of cluster headache. Although case series tended to find that a substantial number of patients improved after ONS, the studies

lacked blinding and comparison groups. RCTs are needed to assess outcomes between ONS and comparators (e.g., to control for a potential placebo effect).

### Summary of Evidence

For individuals who have migraine headaches refractory to preventive medical management who receive ONS, the evidence includes RCTs, systematic reviews of RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Systematic reviews identified 5 sham-controlled randomized trials. Findings from pooled analyses of these RCTs were mixed. For example, compared with placebo, response rates to ONS did not differ significantly but did reduce the number of days with prolonged moderate-to-severe headache. ONS was also associated with a substantial number of minor and serious adverse events. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have non-migraine headaches (e.g., hemicrania continua, cluster headaches) who receive ONS, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Many of the case series had small sample sizes; series with over 25 patients were available only for treatment of cluster headache. Although the case series tended to find that a substantial number of patients improved after ONS, these studies lacked blinding and comparison groups. RCTs are needed to compare outcomes between ONS and comparators (e.g., to control for a potential placebo effect). The evidence is insufficient to determine the effects of the technology on health outcomes.

### Supplemental Information

#### Practice Guidelines and Position Statements

#### Congress of Neurological Surgeons

The 2015 evidence-based guidelines from the Congress of Neurological Surgeons stated: “the use of occipital nerve stimulation is a treatment option for patients with medically refractory occipital neuralgia.”<sup>14</sup> The statement had a level III recommendation based on a systematic review of literature (see Rationale section) that only identified case series.

#### National Institute for Health and Care Excellence

Guidance from the National Institute for Health and Care Excellence (2013) noted that the evidence on occipital nerve stimulation for intractable chronic migraine showed “some efficacy in the short term but very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery.”<sup>15</sup>

#### U.S. Preventive Services Task Force Recommendations

Not applicable.

#### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

#### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT01151631	Occipital Nerve Stimulation in Medically Intractable Chronic Cluster Headache (ICON)	144	March 2019 (active, no recruiting)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03475797	Evaluation of Occipital Nerve Stimulation in Intractable Occipital Neuralgia: A Multicentric, Controlled, Randomized Study	70	December 2020
<b>Unpublished</b>			
NCT03398668	Combined Occipital and Supraorbital Transcutaneous Nerve Stimulation for Treatment of Migraine	58	December 2018 (completed)
NCT01775735 <sup>a</sup>	Occipital Nerve Stimulation (ONS) for Migraine OPTIMISE	28 (actual)	Jan 2017 (terminated early due to low enrollment)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## References

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2. Yang Y, Song M, Fan Y, et al. Occipital nerve stimulation for migraine: a systematic review. *Pain Pract*. Apr 2016;16(4):509-517. PMID 25865962
3. Saper JR, Dodick DW, Silberstein SD, et al. Occipital nerve stimulation for the treatment of intractable chronic migraine headache: ONSTIM feasibility study. *Cephalalgia*. Feb 2011;31(3):271-285. PMID 20861241
4. Silberstein SD, Dodick DW, Saper J, et al. Safety and efficacy of peripheral nerve stimulation of the occipital nerves for the management of chronic migraine: results from a randomized, multicenter, double-blinded, controlled study. *Cephalalgia*. Dec 2012;32(16):1165-1179. PMID 23034698
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11. Leone M, Proietti Cecchini A, Messina G, et al. Long-term occipital nerve stimulation for drug-resistant chronic cluster headache. *Cephalalgia*. Jul 2017;37(8):756-763. PMID 27250232
12. Miller S, Watkins L, Matharu M. Treatment of intractable chronic cluster headache by occipital nerve stimulation: a cohort of 51 patients. *Eur J Neurol*. Feb 2017;24(2):381-390. PMID 27995704
13. Vadivelu S, Bolognese P, Milhorat TH, et al. Occipital nerve stimulation for refractory headache in the Chiari malformation population. *Neurosurgery*. Jun 2012;70(6):1430-1436; discussion 1436-1437. PMID 22418582



14. Sweet JA, Mitchell LS, Narouze S, et al. Occipital nerve stimulation for the treatment of patients with medically refractory occipital neuralgia: Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline. *Neurosurgery*. Sep 2015;77(3):332-341. PMID 26125672
15. National Institute for Health and Care Excellence. Occipital nerve stimulation for intractable chronic migraine [IPG452]. 2013; <https://www.nice.org.uk/guidance/ipg452>. Accessed March 15, 2019.
16. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.125 (April 2019).

### Documentation for Clinical Review

- No records required

### Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.*

#### IE

The following services may be considered investigational.

Type	Code	Description
CPT®	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
	64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
	64569	Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
	64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
	64999	Unlisted procedure, nervous system
HCPCS	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
	L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension

Type	Code	Description
	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
ICD-10 Procedure	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
	00PE0MZ	Removal of Neurostimulator Lead from Cranial Nerve, Open Approach
	00PE3MZ	Removal of Neurostimulator Lead from Cranial Nerve, Percutaneous Approach
	00PE4MZ	Removal of Neurostimulator Lead from Cranial Nerve, Percutaneous Endoscopic Approach
	0JH60BZ	Insertion of Single Array Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
	0JH60CZ	Insertion of Single Array Rechargeable Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
	0JH60DZ	Insertion of Multiple Array Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
	0JH60EZ	Insertion of Multiple Array Rechargeable Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
	0JH63BZ	Insertion of Single Array Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH63CZ	Insertion of Single Array Rechargeable Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH63DZ	Insertion of Multiple Array Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH63EZ	Insertion of Multiple Array Rechargeable Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH80BZ	Insertion of Single Array Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
	0JH80CZ	Insertion of Single Array Rechargeable Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
	0JH80DZ	Insertion of Multiple Array Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
	0JH80EZ	Insertion of Multiple Array Rechargeable Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
	0JH83BZ	Insertion of Single Array Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH83CZ	Insertion of Single Array Rechargeable Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH83DZ	Insertion of Multiple Array Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH83EZ	Insertion of Multiple Array Rechargeable Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

## 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
01/07/2011	BCBSA Medical Policy adoption	Medical Policy Committee
04/08/2015	Coding update	Administrative Review
05/29/2015	Coding update	Administrative Review
10/30/2015	Policy revision without position change	Medical Policy Committee
02/01/2016	Coding update	Administrative Review
07/01/2016	Policy revision without position change	Medical Policy Committee
06/01/2017	Policy revision without position change	Medical Policy Committee
06/01/2018	Policy revision without position change	Medical Policy Committee
06/01/2019	Policy revision without position change	Medical Policy Committee

## Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

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 be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*