BlueCross BlueShield of Alabama

Name of Policy:
Occipital Nerve Stimulation

Policy #: 411
Category: Surgery

Latest Review Date: May 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Occipital nerve stimulation (ONS) delivers a small electrical charge to the occipital nerve in an attempt 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.

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 months. An estimated 45 million Americans experience chronic headaches. For at least half of these people, the problem is severe and sometimes disabling.

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 - 15% in adult men and from 14 - 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 is commonly used for relief of symptoms. Drugs used to prevent migraine include methysergide maleate, propranolol hydrochloride, ergotamine tartrate; amitriptyline, valproic acid, and verapamil.

Hemicrania Continua

Hemicrania continua, also a vascular headache, cause 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 occur mainly in woman, and its true prevalence is not known.

Treatment

Indomethacin usually provides rapid relief of symptoms. Other NSAIDs, including ibuprofen, celecoxib, and naproxen, can provide some relief from symptoms. Amitriptyline and other tricyclic antidepressants are effective in some patients.

Cluster Headache

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 (drooping eyelid), conjunctival injection, lacrimation, rhinorrhea, and, less commonly, facial blushing, swelling, or sweating. Bouts of one headache every other day 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 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 in 1,000.

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.

Policy:

Occipital nerve stimulation does not meet Blue Cross and Blue Shield of Alabama's medial criteria for coverage and is considered **investigational** for all indications.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature search was performed using the MEDLINE database for the period through February 05, 2018.

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 (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs 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

Two systematic reviews of literature on occipital nerve stimulation (ONS) were published in 2015. Both included RCTs and observational studies. The study by Chen et al identified 5 RCTs and 7 case series with at least 10 patients. Three of the RCTs were industry-sponsored, multicenter, parallel-group studies and 2 were single-center crossover trials. All 5 included a sham control group and 1 trial 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 studies did not find a significant difference in response rate between active and sham stimulation (risk ratio [RR], 2.08; 95% confidence interval [CI], 0.50 to 0.55; p=0.31) and a pooled analysis of 3 studies showed a significantly greater reduction in days with prolonged moderate to severe headache (mean difference [MD], 2.59; 95% CI, 0.91 to 4.27; p=0.003).

In their systematic review, Yang et al (2016) identified the same 5 RCTs as Chen. The Yang review was limited to studies conducted with patients with migraine of 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 et al did not pool study findings. Response rates in 3 case series with self-report of efficacy were 100% each, and response rates in the other 2 series were 50% and 89%, respectively. Complication rates in the series ranged from 40% to 100%. The authors noted that the series were subject to biases (e.g., an inability to control for the placebo effect) and that RCT evidence was limited and complication rates were high. The most common complications were lead migration (21% of patients) and infection (7% of patients).

The Occipital Nerve Stimulation for the Treatment of Intractable Chronic Migraine Headache (ONSTIM) trial, a multicenter, randomized feasibility study of occipital nerve stimulation (ONS) for treatment of intractable chronic migraine headache, refractory to preventative medical management, was published in 2011. The trial was designed to evaluate the study design and not powered for a single 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 (AS), 17 to preset stimulation (PS) of one minute per day, and 17 to medical management (MM). At the end of the 3-month trial, 28 patients remained in the AS group, 16 in the PS group and 17 in the MM group. A number of outcome measures were used including responder rate (percentage of patients who achieve 50% or greater reduction in number of headache days per month or a 3-point or greater reduction in average overall pain intensity

compared to baseline). At the 3-month evaluation, the responder rate was 39% in the AS group, 6% in the PS group, and 0% in the MM group. Lead migration occurred in 12 of 51 (24%) of subjects. Three subjects required hospitalization for adverse events (infection, lead migration, and nausea). Limitations of the study include a short observation period and the inability to effectively blind subjects and investigators to treatment group.

This report was followed in 2012 by an industry-sponsored FDA-regulated double-blind trial that randomized 157 patients with chronic migraine refractory to preventive medical management in a 2:1 ratio to active or sham stimulation. Intention-to-treat analysis revealed no significant difference between the groups in the percentage of patients who achieved 50% or greater reduction in visual analog scores (VAS) for pain at 12 weeks (active: 17.1%; control: 13.5%). More patients in the ONS group improved in the number of headache days, migraine-related disability, and direct reports of pain, although the benefits were modest. The most common adverse event was persistent implant site pain. Results from the 52-week open-label extension of this study were published in 2014. Results were reported for the ITT population and for the 125 patients who met criteria for intractable chronic migraine. Twenty-four patients were excluded from analysis due to explantation of the system (n=18) or other 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 50% or greater reduction in headache days and/or pain intensity was observed in 47.8% of patients. Sixty-eight percent of patients were satisfied with the headache relief provided by the device. Seventy percent experienced at least 1 of 183 device-related adverse events, of which 8.6% required hospitalization and 40.7% required surgical intervention. Eighteen percent of patients had persistent pain and/or numbness with the device.

Section Summary: Migraine

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 to sham stimulation, response rates (i.e., ≥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

Hemicrania Continua

Six patients with hemicrania continua received continuous unilateral ONS in a crossover study by Burns et al in 2008. Pain on a 10-point scale was recorded hourly in patient diaries, and the Migraine Disability Assessment Scale (MIDAS) was administered at each follow-up visit. Four of 6 patients reported substantial improvement (80-95%), one reported a 30% improvement, and one reported that pain was worse by 20%. 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. In 2016, Fontaine et al published a prospective case series of 67 patients with chronic cluster headache (CCH). Data were taken from a French database on ONS for treating

refractory headache disorders. Sixty-seven patients with CCH 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 non-responders. 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 non-responders. The series had a large amount of missing data at follow-up.

In 2017, Leone et al published a case series of ONS in 35 patients with CCH. 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 headache number per day and were considered responders. In 12 (40%) patients, improvement was considered stable (i.e., ≤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. 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 of the 15 patients (87%) reported pain relief of greater than 50%. Device-related complications requiring additional surgeries (lead migration, uncomfortable position of generator, wound infection) occurring in 40% of patients during the follow-up period.

Occipital Neuralgia

A 2015 systematic review by Sweet et al identified 9 small case series (fewer than 15 patients each) on the efficacy of ONS for treating medically refractory occipital neuralgia. The authors did not pool study findings. Conclusions cannot be drawn about 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 had small sample sizes; 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 compare 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 occipital nerve stimulation, the evidence includes randomized controlled trials (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 to placebo, response rates to occipital nerve stimulation did not differ significantly but did reduce the number of days with prolonged moderate-to-severe headache. Occipital nerve stimulation 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 occipital nerve stimulation, 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 occipital nerve stimulation, these studies lacked blinding and comparison groups. RCTs are needed to compare outcomes between occipital nerve stimulation 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.

Practice Guidelines and Position Statements

Congress of Neurological Surgeons

A 2015 guideline from the Congress of Neurological Surgeons states: "the use of occipital nerve stimulation is a treatment option for patients with medically refractory occipital neuralgia." The statement had a level III recommendation based on a systematic review of literature, discussed in the Key Points that identified only case series.

National Institute for Health and Care Excellence

2013 guidance from the United Kingdom's National Institute for Health and Care Excellence (NICE) states that the evidence on 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Key Words:

Occipital neurostimulation, Headache, ONSTIM, Migraine, Neuromodulation, implantable pulse generator, Synergy™ IPG, Genesis™ neuromodulation system, Eon™ stimulator, Precision™

Approved by Governing Bodies:

To date, the U.S. Food and Drug Administration (FDA) has not cleared or approved any occipital nerve stimulation (ONS) device for treatment of headache. In 1999, the Synergy™ IPG device (Medtronic), an implantable pulse generator, was approved by FDA 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 FDA for spinal cord stimulation. The Eon™ stimulator has received CE mark approval in Europe for the treatment of chronic migraines.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP: FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:
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	;with connection to 2 or more electrode arrays
64553	Percutaneous implantation of neurostimulator electrodes array; cranial nerve
64555	;peripheral nerve (excludes sacral nerve)
64575	Incision for implantation of neurostimulator electrodes array; peripheral
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 nerve (excludes sacral nerve)
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, 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

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Policy History:

Medical Policy Group, February 2010 **(3)**
Medical Policy Administration Committee, February 2010
Available for comment February 23-April 8, 2010
Medical Policy Group, December 2010: 2011 code update
Medical Policy Group, April 2011; Updated Key Points and References **(3)**
Medical Policy Group, December 2011 **(3):** Updated Key Points and References; Updated 2012 Codes 64553 & 64575
Medical Policy Group, December 2012 **(3):** 2012 update to Description, Key Points and References
Medical Policy Panel, November 2013
Medical Policy Group, January 2014 **(2):** Policy updated with literature review through September 2013. Policy statement unchanged. Information added to Approved by Governing Body. Key Points and References updated.
Medical Policy Group, May 2014 **(5):** 2014 Coding Update: Deleted code L8680 effective July 1, 2014.
Medical Policy Group, June 2014 **(5):** Quarterly 2014 Coding Update: Code L8680 did not delete added back to policy under current codes.
Medical Policy Panel, November 2014

Medical Policy Group, November 2014 **(4):** Updates to Key Points and References. No change to policy statement.
Medical Policy Panel, April 2016
Medical Policy Group, April 2016 **(6):** Updates to Key Points, Approved by Governing Bodies, Coding and References; no change to policy statement.
Medical Policy Panel, April 2017
Medical Policy Group, May 2017 **(6)**: Updates to Description, Key Points and References. No change in policy statement.
Medical Policy Panel, April 2018
Medical Policy Group, May 2018 **(6):** Updates to Description and Key Points.
