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Medical Policy Manual

Topic: Occipital Nerve Stimulation

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Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION[1]

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.

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 (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 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. 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, 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 women, and its true prevalence is not known. 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 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 1.0/1,000. 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.

The U.S. Food and Drug Administration (FDA) has not yet cleared any occipital nerve stimulation device for treatment of headache. The Synergy™ IPG (implantable pulse generator) device from Medtronic 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. The Genesis™ neuromodulation system (St. Jude Medical) is approved by the FDA for spinal cord stimulation and has received CE mark approval in Europe for the treatment of chronic migraines. Medtronic and Boston Scientific Neuromodulation Systems are currently conducting clinical trials of devices.

MEDICAL POLICY CRITERIA

Occipital nerve stimulation is considered **investigational** for all indications, including but not limited to headaches.

SCIENTIFIC EVIDENCE

Assessment of the safety and efficacy of occipital nerve stimulation (ONS) for treatment of headaches requires well-designed and well-executed randomized controlled trials comparing ONS-treated patients with those who received sham treatment or standard of care alone.

Randomized Controlled Trials (RCTs)

- In 2012, Serra and Marchioretto conducted a crossover study in which 30 patients with chronic migraine (100% of patients) and medication overuse headache (85% of patients) were implanted with an ONS and randomized to "Stimulation On" or "Stimulation Off" arms.[2] After one month, or if headaches worsened during the off period, patients were crossed over to the other arm. The mean number of days when patients randomized to the off condition turned on the generators was 4.65 days (range, 1-12 days). Follow-up examinations were conducted at 1, 3, 6, and 12 months after nerve stimulator implantation, during which time the stimulation parameters were adjusted in order to optimize the perception of paresthesia. In addition, the patients were provided with remote controls to modify the stimulation amplitude. At baseline, the average frequency of migraines was 5.8 days per week and the median headache severity was 8 on an 11-point numerical rating scale. Headache intensity and/or frequency were significantly lower in the on arm compared to the off arm and decreased from baseline to each follow-up visit in all patients with Stimulation On. For example, the number of headaches decreased from a median of 6.3 days per week in the off phase to 2.1 days per week in the on phase. The median Migraine Disability Assessment (MIDAS) score decreased from 79 at baseline to 10 at 12-month follow-up. Quality of life measured by the SF-36 significantly improved from baseline throughout the follow-up period. Use of triptans decreased from a median of 20 to 3 doses/month and use of nonsteroidal anti-inflammatory drug (NSAIDs) use decreased from a median of 25.5 to 2 doses/month. There were 2 infections (6.7%) and 3 lead migrations (10%) during the study. This study is limited by the lack of a control group during follow-up and lack of blinding, although blinding of patients may be difficult due to paresthesia with this treatment.

- Also in 2012, Silberstein et. al, published a randomized, controlled trial of patients diagnosed with chronic migraine (CM), implanted with a neurostimulation device and randomized 2:1 to active (n=105) or sham (n=52) stimulation.[3] Authors defined the primary endpoint as the difference in the percentage of responders (defined as patients that achieved a ≥50% reduction in mean daily visual analog scale scores) in each group at 12 weeks. A significant difference was reported at a secondary endpoint of 30% reduction; however, no difference was reported between groups at the primary endpoint of 50% reduction. At a 30% reduction, significant difference in reduction of number of headaches, migraine-related disability, and direct reports of pain relief were reported compared to the sham group, but it is unknown if these results are clinically meaningful considering researchers did not meet their established primary endpoint of at least a 50% reduction in mean daily analog scores. In addition, the overall treatment effect was low, with only 17.1% of the active group and 13.5% of the control group classified as responders.

- A small industry-sponsored feasibility RCT reported preliminary safety and efficacy data on occipital nerve stimulation (ONS) for treatment of medically intractable chronic migraine (CM).[4] However, the findings from this small (n=110) and very short (follow-up=3 months) study must be interpreted with caution due to the exploratory nature of the design:

    - The sample size was chosen to gain experience with ONS and the study was not prospectively powered for efficacy evaluation.
    - No primary end points were specified at the outset; at three months, a range of efficacy

measures were evaluated in comparison to baseline.

Although the findings from this study may provide direction for future research, they do not provide reliable evidence on the clinical utility of ONS. Per the authors, "reliable conclusions regarding efficacy cannot be established on the basis of this study alone."

Nonrandomized Studies

Evidence from nonrandomized studies of occipital nerve stimulation (ONS) for treatment of headaches consists of very small studies (n = 6-37 patients)[5], most of which are non-comparative in nature and have short duration of follow-up. Evidence from these studies is insufficient due to methodological limitation such as nonrandom allocation of treatment, lack of adequate comparison groups, and short-term follow-up, all of which limit conclusions regarding the safety and effectiveness of ONS treatment. Of note, several of these nonrandomized studies reported high rates of ONS revision (20-60%)[6-8] and/or complications (20-40%)[7,8].

Clinical Practice Guidelines

There are no clinical practice guidelines that address the use of occipital nerve stimulation for treatment of headaches.

Summary

There is insufficient evidence to permit conclusion regarding the effectiveness and safety of occipital nerve stimulation (ONS) for treatment of any condition. Current evidence is limited to small case series, two randomized studies and one small crossover study. Valid and reliable conclusions regarding the safety and efficacy of ONS compared to the sham treatment or standard of care alone cannot be made based on this level and quality of evidence. Large, randomized controlled trials with long-term follow-up are needed in order to control for bias, confounding, and placebo effect when evaluating the impact of ONS on health outcomes; however, this type of evidence is not available. Finally, no implantable occipital nerve stimulators have U.S. Food and Drug Administration (FDA) approval at this time. Therefore, ONS is considered investigational for all indications, including as a treatment of headache.

REFERENCES

1. BlueCross BlueShield Association Medical Policy Reference Manual "Occipital Nerve Stimulation." Policy No. 7.01.125
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3. 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*. 2012 Dec;32(16):1165-79. PMID: 23034698
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5. Trentman, TL, Rosenfeld, DM, Vargas, BB, Schwedt, TJ, Zimmerman, RS, Dodick, DW. Greater occipital nerve stimulation via the Bion microstimulator: implantation technique and

stimulation parameters. Clinical trial: NCT00205894. *Pain Physician*. 2009 May-Jun;12(3):621-8. PMID: 19461827
6. Schwedt, TJ, Dodick, DW, Hentz, J, Trentman, TL, Zimmerman, RS. Occipital nerve stimulation for chronic headache--long-term safety and efficacy. *Cephalalgia*. 2007 Feb;27(2):153-7. PMID: 17257236
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CROSS REFERENCES

Interferential Current Stimulation, Durable Medical Equipment, Policy No. 83.07

Spinal Cord Stimulation for Treatment of Pain, Surgery, Policy No. 45

Peripheral Subcutaneous Field Stimulation, Surgery, Policy No. 188

CODES	NUMBER	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
	64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral 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

CODES	NUMBER	DESCRIPTION
		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
	64999	Unlisted procedure, nervous system
	95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., 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 (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
	95971	simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
	95972	complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
	95973	complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (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)
HCPCS	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
	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

CODES	NUMBER	DESCRIPTION
	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