



Clinical Review Criteria Occipital Nerve Stimulation (ONS) for Primary Headache

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Non-Covered Services (L35008) . And for facility-based services billed using a UB form, see Non-Covered Services (L34886)
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Occipital Nerve Stimulation (A-0716) for medical necessity determinations. This service is not covered per MCG guidelines.

See [Deep Brain Stimulation for Primary Headache](#).

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Headache is a major worldwide health problem disabling millions of people and resulting in considerable economic burden. Up to 40% of patients seen in major headache clinics suffer from chronic daily headache. Chronic headache disorders include migraine, cluster headache, cervicogenic headache, occipital neuralgia, and others types of primary headache (Maizels 1998, Jasper 2008).

Cluster headache (CH), an excruciating headache syndrome, is the most common type of trigeminal autonomic cephalalgias, and is thought to be the most severe primary headache disorder. 10-20% of CH patients develop a chronic form in which the attacks persist for more than one year without remissions, or with remissions lasting less than a month. Acute treatment for the attacks includes injectable or intranasal triptans or oxygen inhalation. About one percent will become refractory to medical treatment and fulfill the criteria of intractable headaches. These patients may get some relief with attack treatments, but the disorder could be disabling and may be associated with depression and suicidality (Magis 2007, Leroux 2008).

Migraine headache is a chronic headache that affects about 15% of the population and is one of the most common problems seen in emergency departments and doctors' offices. Migraine is believed to result from changes in the brain and surrounding blood vessels. The attacks typically last from 4-72 hours and vary in frequency from daily to less than one per year. Transformed migraines are chronic daily or almost daily headaches (>15/month) that lasts more than 4 hours. There is no cure for migraine, and medications can only help reduce the frequency and severity of disorder (Bigal 2008).

Cervicogenic headache is a chronic hemicranial pain that usually occurs daily. It usually begins at the suboccipital region and spreads anteriorly to the ipsilateral orbital, frontal, and temporal areas. It is typically unilateral bur

occasionally affects the two sides. It is believed to be due to convergence of upper cervical and trigeminal sensory pathways allowing pain signals to refer from the neck to the trigeminal sensory fields of the head and face. Treatments with pain medication, physical therapy, manipulative treatment, and surgical interventions may provide only some inconsistent temporary relief of pain (Naja 2006).

Various ablative surgical procedures targeting the trigeminal nerve or the cranial parasympathetic outflow have been tried to treat these patients with intractable headaches. These include gamma knife surgery or root section of the trigeminal nerve, trigeminal tractotomy, microvascular decompression of the trigeminal nerve, glycerol injection of the Gasserian ganglion, and others. However, none of these procedures has a consistent effect, and many are associated with serious complications (Magis 2007).

Electrical stimulation of the brain was first attempted late in the 19th century, but its application for pain control began in the 1960s with spinal cord stimulation. The neurostimulation technique for ablating pain is based on the theory that peripheral nerve stimulation can produce specific focal analgesia and anesthesia. In addition, the technique may alter perception of pain by blocking cell membrane depolarization and axonal conduction with directly applied current (Shealy 1967, Lim 2007, Trentman 2008).

In the early 2000s, neurostimulation therapy emerged as a potential treatment option for a variety of different intractable primary headache disorders. This is an invasive device-based approach that has two broad types:

1. Peripheral therapy that involves branches of the occipital nerve: occipital nerve stimulation (ONS), and supraorbital nerve stimulation.
2. Central which refers to deep-brain stimulation (DBS) approaches e.g. hypothalamic deep brain stimulation used for chronic cluster headache (Schwedt 2009).

The occipital nerve stimulators (ONS) are implanted surgically in a 3 phase procedure: Phase 1. An incision is made over the occipital region at the level of the first cervical vertebra for the subcutaneous implantation of bilateral electrodes. These are tunneled in a cephalad direction so that they come to lie across the path of the greater occipital nerve on each side of the head. Phase 2. Confirmation of the electrode position by testing each separately by an external stimulator. The operator gradually increases the amplitude delivered to the electrodes from 0 to 4 v, and the patient is asked to locate and describe any sensation he /she feels. Correct placement is confirmed by the patient describing a vibrating sensation that radiates at least 4 cm cephalad from the base of the skull, on the side of the tested electrode, and Phase 3. Implantation of the stimulator battery in the pectoral, abdominal, or gluteal region, and connecting it to the electrodes via subcutaneously tunneled leads. The procedure is performed under sedation or general anesthesia, however during the second phase the patients are required to be awake and to be able to identify the position of the occipital electrodes when the electric stimulus is applied. Potential complications of the procedure include lead migration, infection, localized pain, muscle spasm, and lack or loss of effect (Lim 2007, Trentman 2008).

The deep brain stimulation (DBS) of the posterior hypothalamus has been investigated in patients with chronic cluster headaches or SUNCT (short-lasting, unilateral, neuralgiform headache attacks with conjunctival injection and tearing). DBS involves MRI guided stereotactic placement of an electrode into the brain (e.g. thalamus, globus pallidus, or subthalamic nucleus). It is typically implanted unilaterally on the side corresponding to the most severe symptoms. The use of bilateral stimulation using two electrodes has been investigated in patients with bilateral, severe symptoms. Initially, the electrode(s) is/are attached to a temporary transcutaneous cable to validate treatment effectiveness and, if effective, the patient returns to surgery several days later for permanent subcutaneous implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator. After implantation, noninvasive programming of the neurostimulation can be adjusted to control the patient's symptoms. The procedures can be performed only by a highly experienced neurosurgeon and may be associated with a small risk of mortality due to intra-cerebral hemorrhage. Before implantation, all patients must undergo complete preoperative neuro-imaging to exclude disorders associated with increased hemorrhagic risk (Leon 2006, Bartsch 2008).

Neither the occipital nerve stimulation nor the deep brain stimulators are approved to date by the U.S. Food and Drug Administration for the treatment or prevention of primary headaches.

Medical Technology Assessment Committee (MTAC)

Occipital Nerve Stimulation (ONS)

08/03/2009: MTAC REVIEW

Evidence Conclusion: The literature on brain stimulation for the treatment of chronic primary headache is limited and does not provide sufficient evidence to determine the efficacy or safety of either occipital or deep brain stimulation therapy for the prevention or treatment of chronic headache. There are no published randomized or

nonrandomized controlled trials on the intervention to date. The empirical studies consist of a few very small case series with no comparison groups and a number of case reports. The outcome measures varied between studies as some reported change in pain and others reported on headache frequency intensity, disability and/or medication use. Popeney and Alo's (2003), the largest series on ONS studied the response to occipital nerve stimulation in a series 25 consecutive patients with transformed migraine. A comparison between pre- and post-implant measurements, showed significant reductions in headache frequency, severity, and disability after the implant. The study was only an observational case series with potential biases, and with no control or comparison group to rule out the placebo effect of the implant.

Articles: The search yielded almost four hundred articles. The majority was review articles, opinion pieces, or dealt with technical aspects the procedure. ONS: There were around 15 small prospective and retrospective case series with patient sizes ranging from 3-25, and a number of case reports on peripheral nerve stimulation. Popeney CA, Alo KM. Peripheral neurostimulation for the treatment of chronic disabling transformed migraine. Headache 2003,43:369-375. See [Evidence Table](#).

The use of Occipital Nerve Stimulation (ONS) for the treatment of primary headache does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Date Reviewed	Date Last Revised
09/16/2009	Added to the annual review because of the Medicare criteria 04/11/2011 ^{MDCRPC} , 02/07/2012 ^{MDCRPC} , 12/04/2012 ^{MDCRPC} , 10/01/2013 ^{MPC} , 08/05/2014 ^{MPC} , 06/02/2015 ^{MPC} , 04/05/2016 ^{MPC} , 02/07/2017 ^{MPC} , 12/05/2017 ^{MPC} , 10/02/2018 ^{MPC}	04/05/2016

^{MDCRPC} Medical Director Clinical Review and Policy Committee
^{MPC} Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
04/05/2016	Adopted MCG A-0716

Codes

CPT: 61885, 61886, 61888, 64553, 64568, 64569, 64570, 95971, 95972, 95973, 95974, 95975, C1767, C1778, C1787, C1816, C1820, C1883, C1897, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689, L8695

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