

# Protocol

## Occipital Nerve Stimulation

(701125)

Medical Benefit	Effective Date: 01/01/11	Next Review Date: 07/15
Preauthorization	No	Review Dates: 09/10, 07/11, 07/12, 07/13, 07/14

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended unless, despite this Protocol position, you feel this service is medically necessary.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### Description

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.

### Background

Implanted peripheral nerve stimulators have been used for treatment of refractory pain for many years but have only recently been 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 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 six 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. 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 nonsteroidal anti-inflammatory drugs (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 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 1.0/1000. 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.

As of September 2013, the U.S. Food and Drug Administration (FDA) has not cleared any occipital nerve stimulation (ONS) 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 the Eon™ stimulator has received CE mark approval in Europe for the treatment of chronic migraines. Medtronic and Boston Scientific Neuromodulation Systems (Precision™) are currently conducting clinical trials of devices.

#### *Related Protocol*

Spinal Cord Stimulation

#### **Policy (Formerly Corporate Medical Guideline)**

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

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

#### **References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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13. National Institute for Health and Care Excellence. IPG452 Occipital nerve stimulation for intractable chronic migraine. 2013. Available online at: <http://publications.nice.org.uk/occipital-nerve-stimulation-for-intractable-chronic-migraine-ipg452>. Last accessed September, 2013.