

POLICY TITLE	OCCIPITAL NERVE STIMULATION			
POLICY NUMBER	MP 2.372			
CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN.			
	☑ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.			
	ASSURE APPROPRIATE LEVEL OF CARE.			
	□ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.			
	□ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.			
	□ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.			

 Assure APPROPRIATE SITE OF TREATMENT OR SERVICE.

 Effective Date:
 1/1/2025

<u>POLICY</u> <u>RATIONALE</u> <u>DISCLAIMER</u> <u>POLICY HISTORY</u> PRODUCT VARIATIONS DEFINITIONS CODING INFORMATION DESCRIPTION/BACKGROUND BENEFIT VARIATIONS REFERENCES

## I. POLICY

Occipital nerve stimulation is considered **investigational** for all indications, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

## Cross-reference:

MP 2.064 Biofeedback and Neurofeedback Therapy MP 6.020 Transcutaneous Electrical Nerve Stimulation Botulinum Toxin

## **II. PRODUCT VARIATIONS**

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI below. Please see additional information below.

**FEP PPO -** Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <u>https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies</u>.

## III. DESCRIPTION/BACKGROUND

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

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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 headaches: 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 of Migraine**

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 β-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 of Hemicrania Continua**

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 one (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



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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 women. One-year prevalence is estimated to be 0 to 1 in 1000.

### **Treatment of Cluster Headache**

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.

## **REGULATORY STATUS**

The U.S. Food and Drug Administration (FDA) 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 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 and the Eon™ stimulator has received CE mark approval in Europe for the treatment of chronic migraines.

#### **IV. RATIONALE**

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## 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 five (5) sham-controlled randomized trials. Findings from pooled analyses of these RCTs were mixed. For example, compared with 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 that the technology results in an improvement in the net health outcome.

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

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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 that the technology results in an improvement in the net health outcome.

### V. DEFINITIONS

N/A

## **VI. BENEFIT VARIATIONS**

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

#### VII. DISCLAIMER

Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

#### VIII. CODING INFORMATION

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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#### Investigational; therefore, not covered:

Procedure	Codes						
61885	61886	64553	64568	64569	64570	64999	L8680
L8681	L8682	L8683	L8684	L8685	L8686	L8687	L8688
L8689							

#### **IX.** References

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## X. POLICY HISTORY

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MP 2.372	<b>12/27/2019 New Policy</b> . Occipital nerve stimulation is considered investigational for all indications. Effective 6/1/2020.			
	<b>12/02/2020 Consensus Review.</b> Policy statements unchanged. References updated.			
	06/03/2021 Consensus Review. No change to policy statement. Updated			
FEP section (removed referenced FEP policy as it no longer active.				
	Language inserted). References updated.			
	06/03/2022 Consensus Review. No change to policy statement. FEP			
language revised. Background, Coding, and References update				
	06/06/2023 Consensus Review. No change to policy statement. Product			
variation and Background updated. Reference added.				
	05/23/2024 Consensus Review. No change to policy statement. References			
	added.			

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