Surgical Deactivation of Headache Trigger Sites

Policy # 00683
Original Effective Date: 08/14/2019
Current Effective Date: 09/14/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Botulinum Toxins is addressed separately in medical policy 00012.

Note: Occipital Nerve Stimulation is addressed separately in medical policy 00253.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers surgical deactivation of trigger sites for the treatment of migraine and non–migraine headache to be **investigational.***

Policy Guidelines

International Headache Society classification criteria (3rd edition, 2013) are listed in Table PG1.

Table PG1. International Headache Society Classification Criteria for Migraines

Classification Criteria
Migraine without aura
Description
Recurrent headache disorder characterized by attacks lasting 4-72 hours.
Diagnostic criteria
A. At least five attacks fulfilling criteria B-D
B. Headache attacks lasting 4-72 hours (untreated or successfully treated)
C. At least two of the following four characteristics: 1. unilateral location

2. pulsating quality 3. moderate or severe pain intensity 4. aggravation by or causing avoidance of routine physical activity (eg walking or climbing stairs)
D. During headache, at least one of the following: 1. nausea and/or vomiting 2. photophobia and phonophobia
E. Not better accounted for by another ICHD-3 diagnosis
Migrainewith aura
Description
Recurrent attacks, lasting minutes, of unilateral fully reversible visual, sensory or other central nervous system symptoms that usually develop gradually and are usually followed by headache and associated migraine symptoms.
Diagnostic criteria
A. At least two attacks fulfilling criteria B and C
B. One or more of the following fully reversible aura symptoms: 1. visual 2. sensory 3. speech and/or language 4. motor 5. brainstem 6. retinal
C. At least two of the following four characteristics: 1. at least one aura symptom spreads gradually over ≥5 minutes, and/or two or more symptoms occur in succession 2. each individual aura symptom lasts 5-60 minutes 3. at least one aura symptom is unilateral 4. the aura is accompanied, or followed within 60 minutes, by headache

D. Not better accounted for by another ICHD-3 diagnosis, and transient ischaemic attack has been excluded.

Adapted from Headache Classification Committee of the International Headache Society (2013; available at http:
//www.ihs-headache.org/ichd-guidelines).

Background/Overview

Migraine is a common headache disorder with a prevalence in the United States of approximately 18% in women and 6% in men. According to the International Headache Society (2013), migraine headache is a recurrent disorder with attacks lasting 4 to 72 hours. Typical features of migraine headaches include unilateral location, pulsating quality, moderate or severe intensity, and associated symptoms such as nausea, photophobia, and/or phonophobia.

Treatment

A variety of medications are used to treat acute migraine episodes. They include medications taken at the onset of an attack to abort the attack (triptans, ergotamines), and medications to treat the pain and other symptoms of migraines once they are established (nonsteroidal anti-inflammatory drugs, narcotic analgesics, antiemetics). Prophylactic medication therapy may be appropriate for people with migraines that occur more than two days per week. In addition to medication, behavioral treatments such as relaxation and cognitive therapy are used to manage migraine headache. Moreover, botulinum toxin type A injections are a U.S. Food and Drug Administrationâ€'approved treatment for chronic migraine (migraines occurring on at least 15 days a month for at least 3 months).

Surgical Deactivation

Surgical deactivation of trigger sites is another proposed treatment of migraine headache. The procedure was developed by a plastic surgeon (Bahman Guyuron, MD), following observations that some patients who had cosmetic forehead lifts reported improvement or elimination of migraine symptoms postsurgery. The procedure is based on the theory that migraine headaches arise due to inflammation of trigeminal nerve branches in the head and neck caused by irritation of the surrounding musculature, bony foramen, and perhaps fascia bands. Accordingly, surgical treatment of migraines involves removing the relevant nerve sections, muscles, fascia, and/or vessels. The treatment is also based on the theory there are specific migraine trigger sites and that these sites can

be located in individual patients. In studies conducted by Guyuron's research group, clinical evaluation and diagnostic injections of botulinum toxin have been used to locate trigger sites. The specific surgical procedure varies according to the patient's migraine trigger site. The surgical procedures are performed under general anesthesia in an ambulatory care setting and take an average of one hour.

Surgical procedures have been developed at four trigger sites: frontal, temporal, rhinogenic, and occipital. Frontal headaches are believed to be activated by irritation of the supratrochlear and suborbital nerves by glabellar muscles or vessels. The surgical procedure involves the removal of the glabellar muscles encasing these nerves. Fat from the upper eyelid is used to fill the defect in the muscles and shield the nerve. Temporal headaches may be activated by inflammation of the zygomatico-temporal branch of the trigeminal nerve by the temporalis muscles or vessels adjacent to the nerve. To treat migraines located at this trigger site, a segment (≈2.5 cm) of the zygomatico-temporal branch of the trigeminal nerve is removed endoscopically. Rhinogenic headaches may involve intranasal abnormalities (eg, deviated septum), which may irritate the end branches of the trigeminal nerve. Surgical treatment includes septoplasty and turbinectomy. Finally, occipital headaches may be triggered by irritation of the occipital nerve caused by the semispinalis capitis muscle or the occipital artery. Surgery consists of removal of a segment of the semispinalis capitis muscle medial to the greater occipital nerve approximately 1 cm wide and 2.5 cm long, followed by insertion of a subcutaneous flap between the nerve and the muscle to avoid nerve impingement.

Non-Migraine Headache
It has been proposed that other types of headaches (eg, tension headaches) may also be triggered by irritation of the trigeminal nerve.

Treatment
Although the mechanism of action is less well established for headaches other than migraine, it is possible that surgical treatment of trigger sites may also be beneficial for some non-migraine headaches.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Surgical deactivation of headache triggers is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

Rationale/Source

Migraine is a common headache disorder that is treated using various medications, which can be taken at the onset of an attack and/or for migraine prophylaxis. Other treatments include behavioral treatments and botulinum toxin injections. Surgical deactivation of trigger sites is another proposed treatment. Surgical deactivation is based on the theory that migraine headaches arise due to inflammation of the trigeminal nerve branches in the head and neck and that specific trigger sites can be identified in individual patients. Surgical deactivation has also been proposed for other types of headaches (eg, tension headaches).

For individuals who have migraine headaches who receive surgical deactivation of headache trigger sites, the evidence includes randomized controlled trials. The relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. Three randomized controlled trials have been published; only one used a sham control and blinded patients to the treatment group. All 3 reported statistically significantly better outcomes at 12 months in patients who received decompression surgery for migraine headache than the control intervention. However, the trials were subject to methodologic limitations (eg, unclear and variable patient selection processes, variability in surgical procedures depending on trigger site). In addition, findings from two trials not blinded or sham-controlled were subject to the placebo effect. Additional sham-controlled randomized studies are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have non-migraine headaches who receive surgical deactivation of headache trigger sites, the evidence includes no published studies. The relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

The American Headache Society (2013) approved a list of 5 items that provide low value in headache medicine. This list was produced as part of the American Board of Internal Medicine Foundation's Choosing Wisely initiative. One of the five recommendations were: "Don't recommend surgical deactivation of migraine trigger points outside of a clinical trial." The 2013 document stated that the value of this procedure is still a research question and that large, multicenter randomized controlled trials with long-term follow-up are needed to provide accurate information on its benefits and harms.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	NCT No.	Trial Name
Ongoing		Ongoing	
NCT02351544	Prospective, Multi-Center Evaluation of the Efficacy of Peripheral Trigger Decompression Surgery for Migraine Headaches	NCT02351544	Prospective, Multi-Center Evaluation of the Efficacy of Peripheral Trigger Decompression Surgery for Migraine Headaches

NCT: national clinical trial.

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References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Surgical Deactivation of Headache Trigger Sites", 7.01.135, March 2020.
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Policy History

Original Effective Date: 08/14/2019
Current Effective Date: 09/14/2020
08/01/2019 Medical Policy Committee review
08/14/2019 Medical Policy Implementation Committee approval. New policy.
08/06/2020 Medical Policy Committee review

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08/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/16/2020 Coding update
Next Scheduled Review Date: 08/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	15824, 15826, 64716, 64722, 64771, 64772, 67900
HCPCS	No codes

ICD-10 Diagnosis	G43.00-G43.919, G44.00-G44.89 Deleted code eff 10/1/2020: R51 Added codes eff 10/1/2020: R51.10, R51.19

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.