FEP 7.01.135 Surgical Deactivation of Headache Trigger Sites

Effective Date: July 15, 2018

Related Policies:
7.01.125 Occipital Nerve Stimulation

Surgical Deactivation of Headache Trigger Sites

Description

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).

FDA REGULATORY STATUS

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.

POLICY STATEMENT

Surgical deactivation of trigger sites is considered **investigational** for the treatment of migraine and non–migraine headache.

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

Migraine with 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).
ICHD-3: International Classification of Headache Disorders, 3rd edition.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have migraine headaches who receive surgical deactivation of headache trigger sites, the evidence includes randomized controlled trials. 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 treatment group. All three 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 2 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. 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

Practice Guidelines and Position Statements

In 2013, the American Headache Society approved a list of 5 items that provide low value in headache medicine.[9] This list was produced as part of the American Board of Internal Medicine Foundation's

Choosing Wisely initiative. One of the 5 recommendations was: “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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY

Date	Action	Description
December 2012	New Policy	Policy created with literature search through August 2012. Surgical deactivation of trigger sites is considered investigational for the treatment of migraine headaches.
December 2013	Update Policy	Policy updated with literature search. References 10-12 added. Non-migraine headache added to policy statement. Title changed to Surgical Deactivation of Headache Trigger Sites.
December 2014	Update Policy	Policy updated with literature review. References 7, 9, and 13-14 added. Policy statement unchanged.
December 2015	Update Policy	Policy updated with literature review through June 23, 2015; references 8 and 15 added. Policy statement unchanged.
June 2018	Update Policy	Policy updated with literature review through December 11, 2017; references 2 and 8 added. Policy statement unchanged.