

Medical Policy



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Title: Surgical Deactivation of Headache Trigger Sites

Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: • With migraine headaches	Interventions of interest are: • Surgical deactivation of headache trigger sites	Comparators of interest are: • Optimal medical management • Botulinum toxin	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Treatment-related morbidity
Individuals: • With non-migraine headaches	Interventions of interest are: • Surgical deactivation of headache trigger sites	Comparators of interest are: • Optimal medical management	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Treatment-related morbidity

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).

OBJECTIVE

The objective of this policy is to evaluate whether surgical deactivation of trigger sites as a treatment of migraine headache and non-migraine headache improves net health outcomes.

BACKGROUND**Migraine Headache**

Migraine is a common headache disorder with a prevalence in the United States of approximately 18% in women and 6% in men.¹ According to the International Headache Society, migraine headache is a recurrent disorder with attacks lasting 4-72 hours.² 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. These include medications that are taken at the outset of an attack to abort the attack (triptans, ergotamines), and medications to treat the pain and other symptoms of migraines once they are established (non-steroidal anti-inflammatory drugs [NSAIDs], narcotic analgesics, antiemetics). Prophylactic medication therapy may be appropriate for individuals with migraines that occur more than 2 days per week. In addition to medication, behavioral treatments such as relaxation and cognitive therapy are used in the management of migraine headache. Moreover, botulinum toxin A injections are a Food and Drug Administration (FDA)-approved treatment for chronic migraine (migraines occurring on at least 15 days per month for at least 3 months).

Surgical Deactivation

Surgical deactivation of trigger sites is another proposed treatment of migraine headaches. The procedure was developed by plastic surgeon Bahman Guyuron, MD, following observations that some patients who had cosmetic forehead lifts often reported improvement or elimination of migraine symptoms post-surgery.^{3,4} 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 that there are specific migraine trigger sites and that these can be located in individual patients. In studies conducted by Dr. 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 individual's migraine trigger site. The surgical procedures are performed under general anesthesia in an ambulatory care setting and take an average of 1 hour.

Surgical procedures have been developed at 4 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 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 zygomaticotemporal 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 (approximately 2.5 cm) of the zygomaticotemporal 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 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 this 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.

REGULATORY STATUS

Surgical deactivation of headache triggers is a surgical procedure and, as such, is not subject to regulation by FDA.

POLICY

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

Policy Guidelines

International Headache Society (IHS) Classification II 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.

RATIONALE

The most recent literature review was conducted through January 27, 2019.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality

of life, and ability to function - including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Headache research involves evaluating subjective outcomes (eg, pain intensity, duration). As a result, blinded, sham-controlled, randomized trials are particularly important in determining efficacy above the placebo effect.

Clinical Context and Test Purpose

The purpose of surgical deactivation as a treatment for migraine or non-migraine headache is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: does the use of surgical deactivation for the treatment of migraine and non-migraine improve net health outcomes?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are patients with migraine or non-migraine headache refractory to medical therapy.

Interventions

The therapy being considered is surgical deactivation for the treatment of migraine or non-migraine headache. 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.

Comparators

The following therapies and practices are currently being used to treat migraine and non-migraine headache; 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. Botulinum toxin type A injections are a U.S. Food and Drug Administration–approved treatment for chronic migraine (migraines occurring on at least 15 days a month for at least 3 months).

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, and treatment-related morbidity.

Timing

Patients with migraine and non-migraine headache who receive surgical deactivation therapy would require acute post-procedure follow-up and at least 6-12 months to ascertain the effect on headache frequency and severity.

Setting

Patients receive surgical deactivation for headache treatment in a tertiary care setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Migraine Headache

Randomized Clinical Trials

To date, two RCTs, from the same research group that includes the surgeon who developed the procedure (Guyuron), and an RCT from Iran have evaluated surgical deactivation of migraine headache trigger sites.

The initial RCT assessing surgical deactivation of migraine trigger sites was published by Guyuron et al (2005); this unblinded trial did not include a sham control.⁵ Eligibility included a diagnosis of migraine headache using the International Classification of Headache Disorders II (ICHD-II) criteria. One hundred patients were assigned to the treatment group and 25 to the control group in a 4:1 allocation. Active treatment patients received up to three injections of botulinum toxin type A (Botox), one at each of their most common trigger sites, to identify a predominant site of headache trigger and potential response to treatment. To be considered candidates for surgery, patients had to have at least a 50% reduction in symptoms for 4 weeks after a botulinum toxin type A injection. Patients in the control group received saline injections instead of botulinum toxin and were ineligible for surgery; for the remainder of the treatment period, they received usual care. For patients in the intervention group, surgery varied by trigger site. For example, for patients with a predominantly frontal trigger migraine headache, the glabellar muscle group was removed to relieve compression of the supraorbital and supratrochlear nerves; for those with a

temporal migraine headache, 3 cm of the zygomatico-temporal branch of the trigeminal nerve was removed; patients with both temporal and frontal migraine headaches underwent both procedures.

Among patients assigned to the treatment group, 91 responded to botulinum toxin type A injection and underwent surgery and 89 (89%) of 100 completed the 12-month follow-up. There was a differential dropout in the 2 groups: 19 (76%) of 25 patients in the control group were evaluated at 12 months. A total of 17 (14%) of 125 randomized patients were excluded from the analysis. In a per-protocol analysis at 12 months, 82 (92%) of 89 patients in the treatment group and 3 (16%) of 19 in the control group experienced significant improvement, defined as at least a 50% reduction in baseline migraine frequency, intensity, or duration. The difference between groups was statistically significant ($p < 0.001$). Thirty-one (35%) of patients in the treatment group and none in the control group reported complete elimination of migraines. Most adverse events following surgery were minor and transient. The most commonly reported events were temporary nasal dryness ($n=12$) and rhinorrhea ($n=11$). Seven patients experienced intense scalp itching that lasted a mean of six months.

Five-year outcomes for patients in the treatment group were reported by Guyuron et al (2011).⁶ Follow-up data were available for 79 patients (87% of those who underwent surgery, 79% of those randomized to the treatment group). Outcomes were reported for 69 patients. The other ten had received additional migraine headache surgery and were excluded from the analysis. At 5 years, 20 (29%) of 69 reported complete elimination of migraine headache, 41 (59%) reported a significant decrease in symptoms, and 8 (12%) reported no significant change. All measured variables improved significantly at five years compared with baseline. For example, mean headache frequency per month decreased from 10.9 to 4.0 ($p < 0.001$). Long-term data were not reported for the control group.

Limitations of the 2005 RCT included lack of blinding, lack of a sham control, and randomization before determining eligibility for surgery. In addition, there was a potential cointervention bias: the surgery group but not the sham group received botulinum toxin injections, which might have had a therapeutic effect. Moreover, about 14% of patients were excluded from the analysis, which could have biased results. Furthermore, findings were not reported separately by surgical procedure. In terms of long-term follow-up, five-year data were reported only for the treatment group.

Guyuron et al (2009) published a double-blind, sham-controlled trial evaluating surgical deactivation of migraine trigger sites in 76 patients.³ Eligibility criteria included a diagnosis of migraine headache according to ICHD-II criteria² and headaches triggered from a single or predominant site, as determined by a headache diary and physical examination. Participants were then given an injection of botulinum toxin type A (Botox) at the prominent site from which migraine pain started. Patients who had a positive response to botulinum toxin type A (ie, at least a 50% decrease in headache symptoms) and in whom headaches recurred after the effect of the botulinum toxin had disappeared were eligible for randomization. The methodology differed in this trial from that of the 2005 RCT (previously described), which randomized patients before receiving diagnostic botulinum toxin type A injections. In addition, Liu et al (2012), (Guyuron coauthored this study), further investigated the method of botulinum toxin injections to select patients for deactivation surgery and found that outcomes were similar in migraine surgery patients who did and did not undergo diagnostic Botox injections.⁴ The Liu et al (2012) analysis

raises questions about the need for the complex patient selection process used in the published RCTs.

In the 2009 RCT, participants were stratified by the predominant site from which headaches were triggered - frontal, temporal, or occipital - and were randomized 2:1 to active or to sham surgery. A total of 317 participants were screened for inclusion; 130 received botulinum toxin type A injections and, based on responses to the injections, 76 were considered eligible for randomization. In each of the three active treatment groups, surgery consisted of exposure and removal of nerves and/or muscles. For patients in the sham group, surgery was limited to exposing the nerves and/or muscles; the integrity of the structures was left intact. The procedures differed according to the predominant headache trigger site and were similar to procedures used in the Guyuron et al (2005) trial. Briefly, patients in the frontal active surgery group underwent removal of the glabellar muscles encasing the supraorbital and supratrochlear nerves. Patients in the temporal active surgery group underwent removal of a segment of the zygomatico-temporal branch of the trigeminal nerve. In the occipital surgery group, a segment of the semispinalis capitis muscle medial to the greater occipital nerve was removed.

Patients kept headache diaries and were seen at 3, 6, 9, and 12 months postsurgery. Seventy-five of 76 patients (49 in the active treatment group, 26 in the sham group) completed the 1-year follow-up. There were 29 patients in the frontal group (19 active treatment, 10 sham), 28 in the temporal group (19 active treatment, 9 sham), and 18 in the occipital group (11 active treatment, 7 sham). Patients remained blinded to their group assignment through 12 months, at which time patients in the sham surgery group were offered the surgical procedure. Key results are displayed in Table 1. Note that, for the frequency, intensity, and duration variables, there were no statistically significant differences by trigger site, so overall results are displayed. Results for the same outcomes from the Guyuron et al (2005) RCT are also summarized in Table 1.

Table 1. Summary of Outcomes for the Guyuron Trials

Outcome Measures	Guyuron et al (2009) ³			Guyuron et al (2005) ⁵		
	Active Surgery (n=49)	Sham Surgery (n=26)	p ^b	Active Surgery (n=89)	Usual Care (n=19)	p ^b
Completely eliminated headaches	28/49 (57.1)	1/26 (3.8)	<0.001	31/89 (35)	0/19 (0)	<0.001
Significant improvement ^a	41/49 (84)	15/26 (58)	0.005	82/89 (92)	3/19 (16)	<0.001
Mean headache frequency, mo	9.9 (6.0)	9.5 (4.4)	0.005	10.9 (0.8)	9.9 (1.7)	<0.001
Baseline (SD)	-7.4 (5.8)	-3.5 (5.4)		3.8 (0.4)	10.2 (1.7)	
12 months (SD) ^c						
Mean headache intensity (1-10 VAS)	6.2 (1.7)	5.5 (1.4)	0.03	8.6 (0.13)	8.8 (0.24)	<0.001
Baseline (SD)	-3.0 (3.5)	-1.3 (2.9)		4.0 (0.3)	7.0 (0.3)	
12 months (SD) ^c						
Mean headache duration			0.43			0.007
Baseline (SD)	0.5 (0.6)	1.7 (5.6)		1.4 (0.14)	1.3 (0.25)	
12 months (SD) ^c	-0.3 (0.5)	-0.9 (4.5)		0.4 (0.05)	1.0 (0.2)	

Values are n/N (%) unless otherwise noted.

SD: standard deviation; VAS: visual analog scale.

^a Significant improvement defined as at least a 50% reduction in migraine frequency, intensity, or duration vs baseline.

^b Between-group p values.

^c In the 2009 study, results are reported as change from baseline.

In the 2009 study, in addition to the between-group differences, there were statistically significant improvements in headache frequency, intensity, and duration from baseline to 12 months within the active surgery group and significant improvements in headache frequency and intensity within the sham surgery group. The improvement in outcomes within the sham group in the 2009 RCT were greater than those seen after usual care in the 2005 RCT, suggesting there might have been a substantial placebo effect associated with the surgery to deactivate trigger sites.

No adverse events were reported in the sham surgery group. All patients in the active treatment group reported some degree of paresthesia immediately after surgery. One patient experienced numbness 12 months after surgery. The most common adverse event in the active treatment group was temporal hollowing in 10 (53%) of 19 patients in the surgery group.

Advantages of the 2009 study included a sham control group and blinded comparison of outcomes in the 2 groups through 12 months postsurgery. Study limitations included small numbers of patients in each subgroup and a lack of reporting patients' use of other migraine treatments (eg, botulinum toxin type A, medications) during the 12-month follow-up. In addition, patient selection involved a long multicomponent selection process, which may be impractical on a widespread basis.

A 2014 review article critically, evaluating the RCTs on surgical deactivation of migraine trigger sites, included the following points⁷:

- The authors of the sham-controlled trial did not mention patients' use of other headache treatments. Postoperative use of medications could have resulted in a reduction in headache frequency; these cases would have been counted as a surgical success in the study.
- In the sham-controlled trial, baseline headache frequency was 9.9 migraines per month in the intervention group and 9.5 migraines per month in the control group and, therefore, the reduction of a small number of migraine episodes per month (which might not be clinically significant) could be considered a surgical success based on the author's criterion of a 50% decrease in frequency.
- Use of the terminology "migraine headaches per month" does not provide information on the number of days per month with migraine headaches or the number of non-migraine headaches per month.
- Patients in the sham group might have guessed their group assignment because of retained movement of the corrugator supercilii, depressor supercilii, and procerus muscles. This could have biased their responses to subjective outcome questions.
- Botulinum toxin type A (Botox) injection is a nonspecific screening tool and can lead to false-positives when used to select patients for migraine surgery because the injections into the peripheral nerves may also modulate pain at central targets.

Omranifard et al (2016) published an RCT comparing surgical deactivation of migraine trigger sites with medical treatment in 50 patients from a single center in Iran.⁸ The trial did not include a sham control and patients were not blinded to treatment group. Patients met ICHD diagnostic criteria for migraine headache and were asked about their most common migraine trigger sites. All patients received injections of botulinum toxin into the frontal, temporal, and occipital trigger sites in a stepwise manner, with the most common site injected first. Investigators did not state how they evaluated patients' responses to botulinum toxin or how patient responses to botulinum

toxin affected their eligibility to participate in the trial. Patients in the medical treatment group (n=25) were prescribed propranolol (80 mg daily) and amitriptyline (100 mg daily). Patients assigned to the surgery group (n=25) underwent decompression surgery in one or any combination of 4 trigger sites (frontal, temporal, septum, and/or occipital) surgeons identified as relevant to their pattern of headaches. Surgical procedures were similar to those used in the Guyuron et al (2005, 2009) RCTs except that a septal surgery option was added.

Trial findings are summarized in Table 2. All 12-month outcomes were significantly better in the surgery group than in the medical treatment group. No adverse events were reported. Interpreting trial findings were influenced by the lack of patient blinding, which raises concerns about subjective and patient-reported outcome measures. Results could have been influenced by the placebo effect. Moreover, it is not clear how patient outcomes data were collected (trialists did not mention patient diaries). Furthermore, surgeries differed by patient trigger sites, which makes it difficult to evaluate any particular surgical procedure.

Table 2. Summary of Outcomes for the Omeranifard Trial

Outcome Measures	Surgery (n=25)	Medical Treatment (n=25)	p ^b
Completely eliminated headaches, n/N (%)	9/25 (36)	1/25 (4)	<0.001
Success rate, n/N (%) ^a	19/25 (76)	10/25 (40)	<0.001
Mean headache frequency, mo			<0.001
Baseline (SD)	15.9 (3.3)	15.2 (3.1)	
12 months (SD)	6.4 (2.3)	10.5 (2.2)	
Mean headache intensity (1-10 VAS)			0.001
Baseline (SD)	8.3 (0.3)	8.4 (0.3)	
12 months (SD)	4.1 (0.2)	6.0 (0.2)	
Mean headache duration, d			<0.001
Baseline (SD)	1.1 (0.5)	1.0 (0.4)	
12 months (SD)	0.5 (0.3)	0.8 (0.3)	

Adapted from Omeranifard et al (2016).⁸

SD: standard deviation; VAS: visual analog scale.

^a Success was defined as at least a 50% reduction in the migraine index score at 12 months vs baseline.

^b Between-group p values.

Section Summary: Migraine Headache

Three RCTs have evaluated surgical deactivation of headache trigger sites. One RCT was double-blind and sham-controlled and the other two did not use a sham control or blinded patients. 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, variability in surgical procedures, the potential use of cointerventions, issues related to patient selection, outcome validation and measurement). In addition, in two trials patients were unblinded and findings subject to the placebo effect. Furthermore, all three were single-center and two were conducted by the same research group headed by the inventor of the procedure. Additional multicenter and sham-controlled randomized studies are needed.

Non-Migraine Headache

No studies were identified that have evaluated surgical deactivation of trigger sites as a treatment of non-migraine headache.

SUMMARY OF EVIDENCE

For individuals who have migraine headaches who receive surgical deactivation of headache trigger sites, the evidence includes RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. Three RCTs have been published; only one used a sham control and blinded patients to a 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 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.

PRACTICE GUIDELINES AND POSITION STATEMENTS

In 2013, the American Headache Society Board of Directors 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 Foundations Choosing Wisely Initiative. One of the 5 recommendations was, “don’t recommend surgical deactivation of migraine trigger points outside of a clinical trial.” The published document states that the value of this procedure is still a research question and that large, multicenter RCTs 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.

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	Planned Enrollment	Completion Date
Ongoing			
NCT02351544	Prospective, Multi-Center Evaluation of the Efficacy of Peripheral Trigger Decompression Surgery for Migraine Headaches	100	Dec 2019

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

There is no specific CPT code for this procedure but it might be reported using one of the following codes:

15824	Rhytidectomy; forehead
15826	Rhytidectomy; glabellar frown lines
20926	Tissue grafts, other (eg, paratenon, fat, dermis)
30130	Excision inferior turbinate, partial or complete, any method
30140	Submucous resection inferior turbinate, partial or complete, any method
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
64716	Neuroplasty and/or transposition; cranial nerve (specify)
64722	Decompression; unspecified nerve(s) (specify)
64771	Transection or avulsion of other spinal nerve, extradural
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

Diagnoses

Experimental / Investigational for all diagnoses related to this medical policy.

REVISIONS

12-11-2014	Policy added to the bcbsks.com web site.
10-13-2015	Updated Description section.
	Updated Rationale section.
	Updated References section.
04-13-2016	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> Removed "headache" to read "Surgical deactivation of trigger sites is considered experimental / investigational for the treatment of migraine and non-migraine headache."
	Updated Rationale section.
	Updated References section.
03-29-2017	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> Under Policy Guidelines, updated International Headache Society classification criteria.
	Updated Rationale section.
	Updated References section.
03-28-2018	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> Updated Policy Guidelines.
	Updated Rationale section.
	Updated References section.
03-27-2019	Updated Description section.
	Updated Rationale section.

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