



Louisiana

Surgical and Ablative Treatments for Chronic Headaches

Policy # 00683

Original Effective Date: 08/14/2019

Current Effective Date: 09/09/2024

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: Closure Devices for Patent Foramen Ovale and Atrial Septal Defects is addressed separately in medical policy 00016.

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

Note: Ablation of Peripheral Nerves to Treat Pain is addressed separately in medical policy 00503.

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 treatment for chronic headaches (including but not limited to chronic migraine headache and chronic tension type headache) to be **investigational**.^{*} This includes, but is not limited to, the following procedures:

- Resection of musculature, including but not limited to the corrugator supercillii muscle, or any soft tissue from the forehead, periorbital, occipital or other facial or scalp areas; **or**
- Manipulation or repositioning of any muscle or other soft tissue within these areas; **or**
- Resection of any portion of the trigeminal nerve or its branches; **or**
- Closure of patent foramen ovale.

Based on review of available data, the Company considers surgical and ablative treatments of occipital neuralgia to be **investigational**.^{*} This includes, but is not limited to, the following procedures for treatment of occipital neuralgia:

- Thermal neurolysis (thermal and cryodenervation); see Medical Policy 00503- Ablation of Peripheral Nerves to Treat Pain
- Neuroplasty;

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- Decompression of the occipital nerves;
- Resection or partial resection of muscle or tissue.

Background/Overview

According to the International Headache Society (IHS), primary headaches are those that are not associated with any demonstrable organic disease, structural or neurologic abnormality. Two types of primary headache are tension-type headache (also known as ordinary headache, stress headache and idiopathic headache) and migraine. Chronic headache, whether migraine or non-migraine, is defined as occurring on 15 or more days per month for more than 3 months.

Tension-type headaches are very common; estimates of lifetime prevalence range from 30% to 70% of the population. Migraines are present in about 28 million people in the United States. The exact pathology of migraines is unknown, but it is felt that a family history of migraine headaches, medications (for example, birth control pills, vasodilators), fatigue, emotional stress and specific foods or alcohol are probable triggers. Migraines manifest as a recurring attack usually lasting for 4-72 hours and involving pain of moderate to severe intensity, often with nausea, sometimes vomiting, sensitivity to light, sound and other sensory stimuli. Management of headaches has consisted largely of pharmacologic treatment (IHS, 2013).

Migraines are generally treated by two approaches: abortive and preventive. The goal of abortive therapy is to prevent a migraine attack or to stop it once it starts. Medications are prescribed to stop a headache during its prodrome stage or once it has begun and may be taken as needed. Preventive treatment is considered if an individual has more than one migraine per week. The goal is to lessen the frequency and severity of the migraine attacks with daily medication.

It has been proposed that activation of peripheral sensory nerves, including the trigeminal nerve, causes release of peptides, (for example, substance P, calcitonin gene-related peptide, neurokinins), resulting in vasodilatation and migraine headache. Also suggested is that trigger points can be identified, particularly in the region of the forehead, at which peripheral nerve activation occurs.

The American Academy of Neurology (AAN) does not address surgical treatment of migraines. Currently their goals of long-term migraine treatment, both pharmacologic and nonpharmacologic are as follows: (AAN, 2004)

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- Reduce attack frequency, severity, and disability;
- Reduce reliance on poorly tolerated, ineffective, or unwanted acute pharmacotherapies;
- Improve quality of life;
- Avoid acute headache medication escalation;
- Educate and enable individuals to manage their disease to enhance personal control of their migraine;
- Reduce headache-related distress and psychological symptoms.

Occipital neuralgia is classified as a secondary headache by the ICHD. Secondary headaches are usually associated with any disease, structural or neurologic abnormality. In this case, accurate diagnosing is important because treatment of the underlying problem usually eliminates the headache.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Surgical and Ablative Treatments of Chronic Headache

In 2012, the American Headache Society (AHS) released a statement urging caution when using surgical interventions for the treatment of headaches, which stated that surgery is a “last-resort” option and is not appropriate for most individuals. They cite a lack of sufficient data on long-term benefit and note that surgical interventions have risks, including that of irreversible side effects.

Resection, manipulation or repositioning of musculature surgery, or nerve resection:

Several randomized controlled trials (RCTs) evaluating surgical deactivation of migraine trigger sites have been published. Guyuron and colleagues (2005) conducted an RCT in 125 individuals diagnosed with migraine headaches. Of these, 100 were randomly assigned to the treatment group and 25 served as controls. The treatment group received sequential Botox injections for identification of headache triggers at the “four most common sites,” beginning with the most common site and proceeding at monthly intervals according to an injection algorithm until all potential trigger points

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were found. Trigger points were found in 91 individuals, 65% of whom had three or four trigger sites identified. A positive response was defined as at least a 50% reduction in intensity and/or frequency of migraine headache lasting at least 4 consecutive weeks, and these individuals were considered surgical candidates. The 25 controls received 0.5 ml. of saline as a “placebo,” however no information was provided regarding their responses and it is unclear which of the four common trigger points were injected in this group. For the treatment group with frontal triggers identified, the glabellar muscle group, including the corrugator supercilii, depressor supercilii and procerus muscles, was removed to relieve compression of the supraorbital and supratrochlear nerves traversing these muscles. Those with temporal migraine underwent endoscopic removal of 3 cm of the zygomaticotemporal branch of the trigeminal nerve to prevent its compression by the temporalis muscle. For those with occipital migraine, a portion of the semispinalis capitis muscle surrounding the greater occipital nerve was removed and the nerve shielded from the muscle with a subcutaneous flap. Participants with migraines triggered from the nasal septum and turbinates underwent septoplasty and inferior and/or middle turbinectomies based on the “intranasal abnormality.”

In the Guyuron (2005) study, there were 89 individuals in the treatment group who completed follow-up. Of these 89, 82 noted at least a 50% reduction in migraine headache frequency and intensity. Post-operatively, 31 reported elimination and 51 reported improvement over a follow-up period of 396 days. In comparison, 3 of the 19 in the control group who completed 1 year follow-up recorded reduction in migraine headaches and no participant observed elimination. Adverse effects from the surgery were minor and transient; however, 23% of those receiving Botox in the temporal area developed hollowing of the temples giving the face an “hour glass” appearance. It was concluded that surgical deactivation of migraine trigger sites can eliminate or significantly reduce migraine symptoms but that additional studies are necessary to clarify the mechanism of action and to determine the long-term results. Drawbacks of this study include lack of information regarding the response of the control group to placebo or sites of injection in this group, and no description of other migraine therapies or any changes in therapy received by either the control or treatment group during the study that might have influenced the outcomes.

In 2010, Guyuron and colleagues reported 5-year follow-up data on the prior study. A total of 79 of the 89 individuals in the treatment group who underwent surgery were followed for 5 years. Ten participants underwent deactivation of additional (different) trigger sites during the follow-up period and were not included in the 5-year analysis. The authors stated that these 10 participants did not affect statistical findings. At 5 years, 62 of the 69 participants (88%) had a positive response to the

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surgery; no data on the response rate in the control group was reported. Twenty individuals (29%) reported complete elimination of migraine headaches, while 41 (59%) noticed a significant decrease and 8 (11%) had no significant change. Compared to the baseline questionnaires of the SF-36 (short form 36 health survey), MSQ (Mental Status Questionnaire), and MIDAS (Migraine Disability Assessment) testing values, all measured variables at 60 months improved significantly ($p < 0.0001$).

In 2009, Guyuron and colleagues conducted a single-center blinded randomized placebo-controlled trial for surgical treatment of frequent moderate to severe migraine headaches. Headache trigger sites were identified by a positive response to botulinum toxin injections. The participants were randomly assigned to a treatment group of actual surgery ($n=49$) or sham group ($n=26$). The treatment group had muscle or nerve tissue removed from their trigger site. The sham surgery group had exposure but not resection of the muscles and nerves through a similar incision. The authors did not specify one or several primary outcomes. They assessed multiple (over 30) outcomes at the $p < 0.05$ level without adjustment for multiple comparisons and thus it is likely that some of the outcomes would have been statistically significant by chance. At 12 months, compared with baseline, the treatment group showed statistically superior outcomes compared to the sham group in 7 comparisons, and no statistical difference in 13 comparisons.

An additional small RCT by Guyuron and colleagues was published in 2015. This study compared two methods of trigger site deactivation: avulsion versus decompression of the zygomaticotemporal branch of the trigeminal nerve. A total of 19 subjects completed the study and were evaluated after a minimum 12 months of follow-up. All subjects experienced greater than 50% improvement in frequency, migraine days, severity, and duration in 34 of the 38 operative sites. There was no statistical significance reported in reduced migraine headache frequency, days, severity, and duration between the two groups. This study did not compare migraine surgery with a different intervention and, therefore, the efficacy of the procedure and a comparator intervention cannot be evaluated.

As summarized in a review by Mathew (2014), limitations of the above studies include “unclear patient selection, lack of sham group in some studies, and the omission of information regarding preventative/abortive medications utilized.” The author concluded, “future trials should address these issues, and should avoid using ambiguous and unclear primary outcomes such as number of migraines, pain intensity, duration, and migraine index which are not validated endpoints in migraine studies.”

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In 2018, the American Society for Plastic Surgery (ASPS) released a position statement on peripheral nerve/trigger site/peripheral nerve surgery for chronic refractory migraine headache. The document concluded, “based on a comprehensive literature search..., peripheral nerve/trigger site surgery for refractory chronic MH [migraine headache] is safe and effective in the treatment of patients with a suspected peripherally-generated/centrally-conducted MH etiology”. The only RCT cited as support for the position was by Guyuron (2005), which is discussed above.

A 2019 meta-analysis by Vincent and colleagues pooled data from three RCTs on trigger site surgery for migraine and found significantly greater odds of elimination of migraine after 1 year in the group receiving surgery compared with a control group (Odds Ratio [OR], 21.46; 95% confidence interval [CI], 5.64 to 81.58, random effects model). There was a wide confidence interval, indicating a lack of precision in the pooled estimate; the pooled analysis has the same limitations as the individual trials, as discussed above by Mathew (2014).

Other systematic reviews of studies evaluating surgery for migraine surgery (Huayllani, 2022; Mangialardi, 2020; Nagori, 2019) did not conduct any pooled analyses comparing outcomes in individuals who had surgery compared with a comparison intervention.

In 2021, Ortiz and colleagues published an analysis of the association between headache surgery and medication use. The study included 129 individuals with a diagnosis of chronic headache who had failed conservative therapy and were about to undergo trigger site deactivation surgery. Participants were given surveys to complete before surgery and 12 months after surgery; questions included headache history and medication use. The primary study endpoint was the number of days per month an individual took prescription medication. Pre-surgery, 124 of 129 individuals (94%) reported taking prescription pain medication. The median number of days of medication use pre-surgery was 30, and 76 individuals (59%) reported daily medication use. At the pre-surgery screening, 39 (31%) individuals reported using opioid pain medication. A total of 97 individuals (75%) completed the 12-month follow-up survey. Among responders, the median frequency of prescription medication use was 10 days per month. This represented a statistically significant change from pre-surgical medication use (67% decrease, $p < 0.001$). Individuals who reported opioid medication use pre-surgery reported a median of 11 days of medication use per month post-operatively. Limitations of this analysis include that it lacked a comparison group of individuals who did not undergo headache surgery, and 25% of study participants did not respond to the post-surgery follow-up survey.

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A 2021 RCT by Bajaj and colleagues compared peripheral neurectomy and medical treatment in 26 individuals with migraine who had benefitted from a local bupivacaine block. The primary outcome was pain, assessed by a visual analogue scale (VAS) and by the migraine headache index (MHI). Compared with baseline, at 6 months the surgical group had significantly lower VAS and MHI scores ($p < 0.001$ for both outcomes). The authors did not discuss blinding; lack of blinding of participants and/or outcome assessment could bias study results.

Closure of patent foramen ovale:

A higher prevalence of patent foramen ovale (PFO) in migraine sufferers compared to the general population has been observed. Foramen closure is theorized to eliminate paradoxical microemboli to the terminal branches of the basovertebral artery or prevent vasoactive substances triggering migraine to bypass the pulmonary filter.

The first RCT to evaluate PFO closure for treatment of migraine was the Migraine Intervention with STARFlex Technology (MIST) trial, published by Dowson and colleagues in 2008. The trial was double-blind and sham-controlled. Eligibility criteria included 18 to 60 years old, history of migraine with aura starting before age 50, at least 5 migraine days per month, at least 7 headache-free days per month and failure of at least 2 classes of migraine medication. A total of 147 individuals were included, 74 assigned to PFO closure and 73 assigned to a sham procedure. The primary efficacy endpoint was cessation of migraine headache at 3 months according to diary data. Three individuals in each group attained this endpoint and the difference between groups was not statistically significant (difference of -0.06%; 95% CI, -6.45 to 6.34; $p = 1.0$). Secondary efficacy endpoints also did not differ significantly between groups. A total of 16 serious adverse events occurred, 8 of which were possibly or definitely related to the study device.

In 2016, Mattle and colleagues published an RCT comparing PFO closure and medical treatment in 107 individuals with migraine with aura. The study, known as the Percutaneous Closure of PFO in Migraine with Aura (PRIMA) trial, had blinded endpoint evaluation but subjects and providers were not blinded. The trial recruited individuals with at least 3 migraine attacks or 5 migraine days per month and less than 15 migraine days per month who had failed at least 2 medications. A total of 107 participants were included, 53 in the treatment group and 54 in the medical management group. The primary efficacy endpoint was reduction in migraine days during months 9 to 12 after the intervention compared with the 3 months prior to the intervention, as recorded in a headache diary.

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There was not a statistically significant difference in the 2 groups on the primary endpoint ($p=0.17$). Moreover, most secondary endpoints did not differ significantly between the 2 groups.

A third RCT, the PREMIUM trial, was published in 2017 by Tobis and colleagues. This study was double-blind and compared PFO closure with medical management. The study included 230 individuals with 6 to 14 migraine days per month who had failed at least 3 migraine medications. The primary efficacy endpoint was a 50% reduction in migraine attacks at months 10-12 compared with a 2-month period at baseline, as measured by participant diaries. A total of 38.5% in the PFO closure group and 32% in the medical management group attained the primary endpoint. The difference between groups was not statistically significant (difference of 6.4%; 95% CI, -6.2 to 19.0). Findings on secondary outcomes were mixed. Several secondary endpoints, decrease in the mean number of migraine days per month and complete cessation of migraine, favored the PFO closure group. However, there were no significant differences between groups on other secondary outcomes, change in the migraine disability score and the proportion of participants with at least a 75% reduction in migraine attacks.

A meta-analysis of the three RCTs described above was published by Elbadawi and colleagues in 2019. Primary outcomes varied among the trials and meta-analyses were conducted on a number of outcomes. Findings of the meta-analyses were mixed. For example, a pooled analysis found a significantly greater reduction in monthly migraine attacks with PFO closure versus a control intervention (standardized mean difference [SMD], 0.25; 95% CI, 0.06 to 0.43; $p=0.01$). However, another pooled analysis did not find a statistically significant difference between groups in complete resolution of migraine headache attacks (OR, 3.67; 95% CI, 0.66 to 20.41; $p=0.17$).

In addition to the RCTs, a number of observational studies evaluating PFO closure for treatment of migraine have been published. A 2017 meta-analysis by Shi and colleagues included eight observational studies on the effect of PFO closure on migraine that distinguished between migraine with and without aura. Only one of the eight studies was prospective (Rigatelli, 2010). A meta-analysis of the eight studies found a significantly greater effect of PFO closure on migraine without aura compared with migraine with aura (OR, 2.5; 95% CI, 1.09 to 5.73). The meta-analysis did not compare PFO closure to other treatments for migraine so conclusions about the efficacy of PFO closure cannot be drawn from this analysis.

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None of the three RCTs that studied PFO closure for migraine found a significant effect of the procedure on the study's primary outcome (reduction or cessation of migraines). All RCTs were multicenter and had blinded endpoint evaluation. In addition, most secondary outcomes did not find a significant benefit of PFO closure. Observational studies that evaluate PFO closure in individuals with migraine are limited by lack of controls and blinding, and most studies were retrospective.

A 2022 meta-analysis by Zhang and colleagues included the MIST, PRIMA and PREMIUM RCTs, discussed above, as well as 8 retrospective case series. A meta-analysis of data from the three RCTs found statistically significant benefits of surgery versus the control intervention on reduction in the number of migraine attacks and resolution of migraine with aura, but no statistically significant difference between groups in reduction in complete resolution of migraine headache. The analysis did not take into consideration the primary versus secondary outcomes of the individual studies.

Surgical and Ablative treatments of Occipital Neuralgia

Various treatments and procedures have been proposed for treatment of occipital neuralgia, however, the published literature addressing these treatments consists of small, nonrandomized studies, case reports and case series, as well as retrospective studies and reviews.

Neurolysis

In a retrospective chart review, Ducic and colleagues (2009) reported on 206 consecutive subjects undergoing neurolysis of the greater or, less commonly, excision of the greater and/or lesser occipital nerves. Preoperative and postoperative visual analogue pain scores and migraine headache indices were measured. Success was defined as a reduction in pain of 50% or greater. Minimum duration of follow-up was 12 months. Of the 206 subjects, 190 underwent greater occipital nerve neurolysis (171 bilateral), 12 subjects underwent greater and lesser occipital nerve excision and 4 underwent lesser occipital nerve excision alone. The authors found that 80.5% of the subjects experienced at least 50% pain relief and 43.4% of the subjects experienced complete relief of headache. Mean preoperative pain score was 7.9 ± 1.4 . Mean postoperative pain was 1.9 ± 1.8 . This study is limited by lack of a control group.

A much smaller case series was published by Gille and colleagues in 2004. The investigators examined surgical treatment of greater occipital neuralgia by neurolysis of the greater occipital nerve and sectioning of the inferior oblique muscle in 10 individuals. Of this group, 3 individuals had anatomic anomalies. Mean follow-up was 37 months. The results of the treatment were assessed

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according to three criteria: (1) degree of pain on a VAS; (2) consumption of analgesics; and (3) the degree of satisfaction at follow-up. The mean VAS score was 80/100 before surgery and 20/100 at last follow-up. Consumption of analgesics decreased in all individuals. The small size, short follow-up and lack of a control group limits the validity of the results of this study.

Decompression

In 2011, Ducic and colleagues reported on 25 individuals with documented bilateral occipital neuralgia-related chronic headaches who underwent peripheral nerve surgery with decompression of the greater occipital nerve bilaterally, including the area of its intersection with the occipital artery. All individuals were evaluated intraoperatively for evidence of arterially mediated greater occipital nerve compression and the configuration of the nerve-vessel intersection. Pathologic evaluation of the occipital artery from 15 individuals showed vasculitis. The purpose of the study was to show that mechanical (and not primary inflammatory) irritation of the nerve by the occipital artery is an important theoretical cause for otherwise idiopathic cases. It was not designed to evaluate the efficacy of decompression surgery.

In 2023, Pietramaggiore and Scherer published a retrospective chart review of 87 individuals who underwent surgical decompression of the occipital nerves for treatment of headache at a single center. Outcome measures were those that were noted in the chart before surgery and at the time of the last visit (minimum duration since surgery was 12 months). Chronic pain days decreased from an average of 25 days per month to 4.3 days per month ($p < 0.01$). Individuals reported that pain intensity decreased from an average of 3.7 out of 10 to 0.7 out of ten ($p < 0.01$). In addition, use of nonsteroidal anti-inflammatory drugs decreased from 25 pills per month to 8 pills per month ($p < 0.01$). Controlled studies are needed to determine whether decompression surgery improves outcomes in individuals with neuralgia-related chronic headaches.

Pulsed Radiofrequency

Vanelderen and colleagues (2010) conducted a prospective study on 19 participants receiving pulsed radiofrequency (PRF) for the treatment of occipital neuralgia with a 6-month follow-up. Participants with clinical findings suggestive of occipital neuralgia and a positive test block of the occipital nerves with 2 ml of local anesthetic underwent a PRF procedure of the culprit nerves. Mean scores for pain, quality of life, and medication intake were measured at 1, 2, and 6 months post procedure. Mean VAS and median Medication Quantification Scale scores declined by 3.6 units ($p = 0.002$) and 8 units ($p = 0.006$), respectively, during 6 months. Approximately 52.6% of the participants reported

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a score of six (pain improved substantially) or higher on the Likert scale after 6 months. No complications were reported. Study limitations include that it had a small sample size and did not include a control group.

Huang and colleagues (2012), in a retrospective data analysis, evaluated PRF for the treatment of occipital neuralgia. A total of 102 individuals with a primary diagnosis of occipital neuralgia were treated with PRF of the greater and/or lesser occipital nerve. A positive primary outcome was predefined as 50% or greater pain relief lasting at least 3 months. The secondary outcome measure was procedural satisfaction. Fifty-two (51%) subjects experienced 50% or greater relief of pain and satisfaction with treatment lasting at least 3 months. The study was uncontrolled and did not report on treatment efficacy beyond 3 months; larger controlled trials reporting longer-term outcomes are needed.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Headache Society

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 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.

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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

As of December 2023, no ongoing or unpublished trials were identified that might influence this review.

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Websites for Additional Information

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08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. New policy.
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/16/2020	Coding update
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Title changed from “Surgical Deactivation of Headache Trigger Sites” to “Surgical and Ablative Treatments for Chronic Headaches”. Extensive policy revision. Added a reference to medical policy 00503 to the thermal neurolysis investigational bullet for surgical and ablative treatments of occipital neuralgia.
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2025

Coding

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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, 64732, 64734, 64744, 64771, 64772, 64999, 67900, 93580
HCPCS	No codes
ICD-10 Diagnosis	G43.001-G43.919, G44.001-G44099, G44201-G44229, G501, M5481, R510-R519

*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

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diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with 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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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