Sphenopalatine Ganglion Block for Headache

Policy # 00563
Original Effective Date: 08/23/2017
Current Effective Date: 09/12/2022

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 Toxin is addressed separately in medical policy 00012.

Note: Transcutaneous Electrical Nerve Stimulation is addressed separately in medical policy 00142 Electrical Nerve Stimulation Devices.

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

Note: Surgical Deactivation of Headache Trigger Sites is addressed separately in medical policy 00683.

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 sphenopalatine ganglion (SPG) blocks for all indications, including but not limited to the treatment of migraines and non-migraine headaches to be investigational.*

Background/Overview
Headaches and Headache Treatments
Headaches are common neurologic disorders and are among the top reasons why patients seek medical care. Headaches affect approximately 50% of the general population in a given year and over 90% of people have a lifetime history of headache. The 2 most common types of headache are migraines and tension-type headaches.

Migraines are the second-most common headache disorder, with a 1-year migraine prevalence of approximately 12% in the United States. They are characterized by severe pain on 1 or both sides of the head, nausea, and, at times, disturbed vision. Migraines can be categorized by headache

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frequency, and by the presence or absence of aura. Chronic migraine is defined as attacks on at least 15 days per month for more than 3 months, with features of migraine on at least 8 days per month.

Tension-type headaches have a prevalence of approximately 40%. Diagnostic criteria include the presence of at least 2 of the following 4 characteristics: bilateral headache location, nonpulsating pain, mild-to-moderate intensity, and headache not aggravated by physical activity; lasting between 30 minutes and 7 days; and not accompanied by nausea, vomiting, photophobia, or phonophobia.

Cluster headaches are less common than tension or migraine headaches, with an estimated prevalence of 0.1% of the population. They are characterized by severe unilateral orbital, supraorbital, and/or temporal pain that also includes other symptoms in the eye and/or nose on the same side (eg, rhinorrhea, eyelid edema or drooping).

Postdural puncture headache (PDPH), is a common complication of lumbar puncture. This headache also occurs with low cerebrospinal fluid volume from a leak at the site of the dural puncture, resulting in low cerebrospinal pressure and intracranial hypotension. Patients undergoing epidural anesthesia are also at risk for PDPH due to unintended dural puncture, which has been reported to occur in <1% to 6% of obstetric patients. PDPH is characterized by a bilateral frontal or occipital headache that worsens with sitting or standing and is relieved in the supine position. Associated symptoms may include nausea, neck stiffness, low back pain, tinnitus, and visual disturbances. The reported incidence of PDPH as a complication of lumbar puncture is variable, ranging from 10% to 40% of lumbar puncture procedures. Incidence may be as low as 2% when small gauge, non-cutting needles are used.

A variety of medications are used to treat acute migraine episodes. These include medications taken at the onset 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, antiemetics). Prophylactic medication therapy may be appropriate for people with migraines that occur more than 2 days per week. Botulinum toxin type A injections are a U.S. Food and Drug Administration (FDA) approved prophylactic treatment for chronic migraine. Several calcitonin-gene related peptide antagonists are available as FDA-approved treatment options for acute and prophylactic treatment of migraine. In addition to medication, behavioral treatments (eg, relaxation, cognitive therapy) are used to manage migraine headache.
Severe acute cluster headaches may be treated with abortive therapy, including breathing 100% oxygen and triptan medications. Other medications used to treat cluster headaches include steroids, calcium channel blockers, and nerve pain medications. Due to the severity of pain associated with cluster headaches, patients may seek emergency treatment. Tension-type headaches are generally treated with over the counter pain medication.

**Sphenopalatine Ganglion Block**
Sphenopalatine ganglion (SPG) blocks are a proposed treatment option for chronic migraines and some severe non-migraine headaches. The SPG is a group of nerve cells located behind the bony structures of the nose. The nerve bundle is linked to the trigeminal nerve, the primary nerve involved in headache disorders. The SPG has both autonomic nerves, which in this case are associated with functions such as tearing and nasal congestion, and sensory nerves, associated with pain perception. These blocks involve topical application of local anesthetic to mucosa overlying the SPG. The rationale for using SPG blocks to treat headaches is that local anesthetics in low concentrations could block the sensory fibers and thereby reduce pain while maintaining autonomic function.

The proposed procedure for SPG blockade is to insert intranasally a catheter that is attached to a syringe carrying local anesthetic (eg, lidocaine, bupivacaine). Once the catheter is in place, the local anesthetic is applied to the posterior wall of the nasal cavity and reaches the SPG. Originally, SPG blocks were done by inserting a cotton-tipped applicator dabbed with local anesthetic into the nose; this technique may be less accurate and effective than the currently proposed procedure. Neurostimulation of the SPG and SPG blockade with radiofrequency lesioning have been used outside of the United States, but these treatments are not cleared or approved by the FDA.

Three catheter devices are commercially available in the United States for performing SPG blocks. The catheters have somewhat different designs but all are attached to syringes to deliver local anesthetic. The catheters are inserted intranasally and, once in place, the local anesthetic is applied through the catheter. With 2 of the 3 commercially available catheters (the SpenoCath®, Allevio™), patients are positioned on their back with their nose pointed vertically and their head turned to the side. With the Tx360® device, patients remain seated.

The optimal number and frequency of SPG treatments is unclear. Information from the American Migraine Foundation suggests that the procedure can be repeated as often as needed to control pain.
A randomized controlled trial has described a course of treatment for migraines consisting of SPG blocks twice a week for 6 weeks (total, 12 treatments).

Sphenopalatine ganglion blocks are proposed for both short- and long-term treatment of headaches and migraines. When used in the emergency setting in patients with severe acute headaches, the goal of treatment is to abort the current headache while the patient is in the emergency department. In the randomized controlled trial that provided a 6-week course of treatment with SPG blocks for chronic migraine (mentioned above), short-term outcomes were assessed up to 24 hours after each treatment, and the duration and frequency of chronic migraines were assessed at 1 and 6 months after the course of treatment.

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)
The Tx360 Nasal Applicator (Tian Medical), the Allevio SPG Nerve Block Catheter (JET Medical), and the SpenoCath (Dolor Technologies) are considered class I devices by the FDA and are exempt from 510(k) requirements. This classification does not require submission of clinical data on efficacy but only notification of FDA prior to marketing. All 3 devices are used to apply numbing medication intranasally.

**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.

Chronic migraine and severe headaches are common conditions and the available treatments are not universally effective. A proposed treatment option is blocking the sphenopalatine ganglion (SPG) nerve by applying topical anesthetic intranasally. Several catheters approved by the U.S. Food and Drug Administration are available for the SPG blocking procedure.
Summary of Evidence

For individuals who have chronic migraine who receive SPG block(s), the evidence includes a randomized controlled trial (RCT) and a case report. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The randomized trial evaluated a regimen of 12 SPG blocks over 6 weeks and was double-blind and placebo-controlled. The trial found significantly greater short-term (up to 24 hours) benefits from active treatment than from placebo. There were no significant long-term effects (ie, 1 and 6 months after 12 treatments), although the trial was underpowered to detect longer term efficacy. Given that SPG blocks are being proposed as a preventive therapy for chronic migraines, evidence demonstrating reduced migraine frequency, severity, or other objective outcomes from robust trials is still needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe acute headache treated in the emergency setting who receive SPG block(s), the evidence includes 1 RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The randomized, double-blind, placebo-controlled trial evaluated a single SPG block for severe acute headache of mixed etiologies. There was no statistically significant difference between active treatment and placebo for the primary outcome (pain reduction 15 minutes postintervention). The trialists did not collect pain data again until 24 hours posttreatment, at which time significantly more patients were headache-free in the active treatment arm than in the placebo arm. Additional studies, preferably RCTs, are needed to determine whether SPG blocks are an effective treatment in the emergency setting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cluster headache who receive SPG block(s), the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two small case series, both of which evaluated an approach for intranasal SPG blocks that differs from the intervention currently available in the United States, were identified. In these series, 40% to 50% of patients experienced complete symptom relief for a variable length of time and about 20% had treatment-related complications. However, it is not clear from these series the degree to which the procedures evaluated differ in safety and efficacy from an intranasal SPG block using a device cleared by the U.S. Food and Drug Administration. Additional studies, preferably RCTs, are needed to evaluate SPG blocks for treating cluster headaches. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
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For individuals who have postdural puncture headache who receive SPG block(s), the evidence includes a RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The small randomized, double-blind, placebo-controlled trial evaluated a single SPG block for postdural puncture headache in patients with both intended and accidental dural punctures. There was no statistically significant difference between active treatment and placebo for the primary outcome (median pain intensity in the upright position 30 minutes postintervention). Active rescue blocks were required in 65% of patients in each group, administered within an average of 1.4 hours for the active group and 1.5 hours for the placebo group. There was no statistically significant difference between active treatment and placebo for the number of patients requiring definitive treatment with an epidural blood patch. Additional studies, preferably RCTs, are needed to evaluate SPG blocks for treating postdural puncture headaches. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**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 Academy of Pain Medicine**

The American Academy of Pain Medicine (2021) conducted a systematic review to develop practice recommendations for use of percutaneous interventional strategies for the preventive treatment of migraine. Sphenopalatine ganglion blocks received a weak recommendation for chronic migraine prevention based on a very low certainty of evidence. The only therapy evaluated in the guideline that received a strong recommendation for chronic migraine prevention was onabotulinumtoxinA.

**American Headache Society**

The American Headache Society guideline (2016) on the treatment of cluster headache includes subcutaneous sumatriptan, zolmitriptan nasal spray, and high flow oxygen as Level A (established as effective) acute treatment recommendations. Sphenopalatine ganglion stimulation is rated as a Level B (probably effective) acute treatment recommendation. However, the recommendation for
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Sphenopalatine ganglion stimulation was based on 1 randomized controlled trial that evaluated an implanted, on-demand, acute electrical stimulation device of the SPG, rather than a catheter device used to apply local anesthetic. There are no Level A recommendations for reducing the frequency of cluster headaches in the guideline.

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 ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
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<tr>
<td>NCT03337620a</td>
<td>A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel 20 Week Study of the Efficacy and Safety of the Tx360‡ Nasal Applicator for Transnasal Sphenopalatine Ganglion Block in the Treatment of Chronic Migraine</td>
<td>180</td>
<td>Jun 2021 (recruiting)</td>
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<tr>
<td>NCT03560349</td>
<td>A Multicenter Double Blinded Randomized Controlled Trial of the Efficacy of the Sphenopalatine Ganglion Block for the Treatment of the Postdural Puncture Headache After Labor Epidural</td>
<td>90</td>
<td>Jun 2021 (enrolling by invitation)</td>
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<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Description</th>
<th>Patients</th>
<th>Date</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>NCT04255420</td>
<td>Sphenopalatine Ganglion Blocks for Headaches in the Emergency Department</td>
<td>84</td>
<td>Jun 2021</td>
<td>(recruiting)</td>
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<tr>
<td>NCT02090998</td>
<td>Sphenopalatine Ganglion Nerve Block vs. Elavil for Treatment of Transformed Migraines</td>
<td>200</td>
<td>Jul 2021</td>
<td>(unknown)</td>
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<tr>
<td>NCT03112720</td>
<td>A Comparison of the Efficacy of Sphenopalatine Ganglion (SPG) Block With 5% Lidocaine Versus Epidural Blood Patch (EBP) for the Treatment of Post-Dural Puncture Headache (PDPH)</td>
<td>500</td>
<td>Jul 2021</td>
<td>(unknown)</td>
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<tr>
<td>NCT03984045</td>
<td>Sphenopalatine Ganglion Block for Treating Acute Frontal Migraine Headache in Pediatric Patients</td>
<td>72</td>
<td>Dec 2021</td>
<td>(recruiting)</td>
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<tr>
<td>NCT04069897</td>
<td>Botulinum Toxin Type A Blockade of the Sphenopalatine Ganglion in Treatment-refractory Chronic Migraine (MiBlock)</td>
<td>170</td>
<td>Dec 2024</td>
<td>(recruiting)</td>
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<tr>
<td>NCT03944876</td>
<td>Botulinum Toxin Type A Blockade of the Sphenopalatine Ganglion in Treatment-refractory Chronic Cluster Headache (BASIC)</td>
<td>112</td>
<td>Sep 2025</td>
<td>(recruiting)</td>
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**Unpublished**

<table>
<thead>
<tr>
<th>Trial ID</th>
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<th>Patients</th>
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<th>Status</th>
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<tr>
<td>NCT03666663</td>
<td>UCSF Sphenopalatine Ganglion Block Study- a Randomized Double Blind Placebo Controlled Trial to Compare Nasal Anesthetics for Migraine Prevention in Adults (SPGblock)</td>
<td>10</td>
<td>Aug 2021</td>
<td>(active, not recruiting)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.  
a Denotes industry-sponsored or -cosponsored trial.
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References
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Policy History

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Current Effective Date:   09/12/2022
08/03/2017   Medical Policy Committee review
08/09/2018   Medical Policy Committee review
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08/15/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2019 Medical Policy Committee review
08/14/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/07/2020 Coding update
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
08/04/2022 Medical Policy Committee review
08/10/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2023

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 2021 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:

<table>
<thead>
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<th>Code Type</th>
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<tr>
<td>CPT</td>
<td>64505, 64999</td>
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<tr>
<td>HCPCS</td>
<td>No codes</td>
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<tr>
<td>ICD-10 Diagnosis</td>
<td>G43.001-G43.919, G44.001-G44.029, G44.031-G44.89, R51.0, R51.9</td>
</tr>
</tbody>
</table>

*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 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.
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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.