

7.01.159 Sphenopalatine Ganglion Block for Headache	
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Section: 7.0 Surgery	Page: Page 1 of 14

Policy Statement

- I. Sphenopalatine ganglion blocks are considered **investigational** for all headache indications, including but not limited to the treatment of migraines and non-migraine headaches.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

This procedure is sometimes reported with the following CPT code, but, in the absence of an actual injection, this code is incorrect:

- **64505:** Injection, anesthetic agent; sphenopalatine ganglion

The American Medical Association recommends using the following to unlisted code to report this procedure:

- **64999:** Unlisted procedure, nervous system

It was mentioned that this service is reported by some providers with the following CPT code for trigeminal block:

- **64400:** Injection, anesthetic agent; trigeminal nerve, any division or branch

Description

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.

Related Policies

- Occipital Nerve Stimulation
- Surgical Deactivation of Headache Trigger Sites

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

The Tx360 Nasal Applicator (Tian Medical), the Allevio SPG Nerve Block Catheter (CureMed), and the Spheno Cath (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

Background

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.¹ 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.² They are characterized by severe pain on one or both sides of the head, nausea, and, at times, disturbed vision. Migraines can be categorized by headache 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.³

Tension headaches have a prevalence of approximately 40%.² Diagnostic criteria include the presence of at least two of the following characteristics: bilateral headache location, nonpulsating pain, mild-to-moderate intensity, and headache not aggravated by physical activity.³

Cluster headaches are less common than tension or migraine headaches, with an estimated prevalence of 0.1% of the population.² 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 (e.g., rhinorrhea, eyelid edema or drooping).

Treatment

A variety of medications are used to treat acute migraine episodes. They include medications taken at the onset of an attack to abort the attack (triptans, ergotamines) and medications to treat the pain and other symptoms of migraines once they are established (nonsteroidal anti-inflammatory drugs, antiemetics). Prophylactic medication therapy may be appropriate for people with migraines that occur more than 2 days per week. In addition to medication, behavioral treatments (e.g., relaxation, 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.

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.

SPG 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 (e.g., 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,⁴ but these treatments are not cleared or approved by the U.S. Food and Drug Administration.

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.⁵

The company marketing the Tx360[®] device proposes its use in the context of the MiRx[™] protocol.⁶ This 2-part protocol includes a medical component for immediate pain relief and a physical component to reduce headache recurrences. The medical component involves clinical evaluation and, if the patient is considered eligible, an SPG block procedure. The physical component can include any of a number of approaches such as physical therapy, ergonomic modifications, massage, and dietary recommendations.

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.⁵ 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).

SGB 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Chronic Migraine

Clinical Context and Therapy Purpose

The purpose of sphenopalatine ganglion (SPG) block(s) in individuals who have chronic migraine headache is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic migraine headache.

Interventions

The therapy being considered is a SPG block.

Comparators

The following therapies and practices are currently being used to treat chronic migraine headache: medication, self-management (eg, relaxation, exercise), and botulinum toxin injection.

Outcomes

The general outcomes of interest are reductions in migraine frequency, intensity, and medication use. Treatment-related adverse events are minor. A series of injections may be given over several weeks, with follow-up over months to monitor for treatment effect and durability.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- Due to a typically high placebo response rate in patients with headache, placebo-controlled trials were preferred.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

Findings from a double-blind, placebo-controlled RCT that evaluated SPG blocks to treat chronic migraine were published in 2 publications by Cady et al (2015). The first publication⁸ reported on the primary outcome measure and key secondary outcomes, and the subsequent publication⁹ reported on supplemental secondary outcomes and longer term follow-up. The trial included patients who met International Classification of Headache Disorders-II diagnostic criteria for chronic migraine¹⁰, and

had chronic migraine for at least 3 months. Patients could use concomitant headache medication, but had to agree not to change medication use during the study period. Following an initial 28-day baseline period to confirm the diagnosis of chronic migraine, patients were randomized 2:1 to treatment with bupivacaine 0.5% or saline (placebo) applied using the Tx360 device. Patients received a series of 12 treatments - 2 treatments a week for 6 weeks. The primary outcome was change in pain severity, measured using a 0-to-10 numeric rating scale. Pain severity was assessed 15 minutes, 30 minutes, and 24 hours after each treatment. Key secondary outcome measures were the Patient's Global Impression of Change, the Headache Impact Test (HIT-6) questionnaire, and patient satisfaction with treatment. In addition, patients kept headache diaries throughout the study.

Forty-one patients met eligibility criteria and had chronic migraine diagnoses confirmed during the baseline period.⁸ These patients were randomized to bupivacaine (n=27) or to placebo (n=13). Mean baseline scores on the numeric rating scale were 4.8 in the bupivacaine group and 4.5 in the placebo group. When findings for all treatments were pooled, patients in the bupivacaine group reported a significantly greater reduction in numeric rating scale scores than the placebo group at 15 minutes, 30 minutes, and 24 hours after treatment. Bupivacaine-treated patients also had significantly lower Patient's Global Impression of Change scores than saline-treated patients at 30 minutes and 24 hours posttreatment. No statistically significant between-group differences were reported in HIT-6 scores or in average acute medication use. Only 1 serious adverse event was reported and it was not treatment-related.

The second publication by Cady et al reported on 1- and 6- month follow-up results and on supplemental secondary end points.⁹ To control for multiple comparisons, the cutoff for statistical significance for the supplemental secondary end points was $p < .01$. There were no statistically significant differences between groups in the reported supplementary secondary outcomes. These outcomes included the number of headache days per month, the mean pain score, and quality of life measures. A post hoc power analysis revealed that the trial was underpowered to detect significant differences in secondary outcomes. Some results were suggestive of a long-term effect. For example, the bupivacaine group had a lower, albeit nonsignificant, number of headache days in the month posttreatment (17 days) than the placebo group (23 days). However, a trial with a larger sample size would be needed to confirm whether 1- or 6-month results are significantly better after bupivacaine than after placebo treatment.

Section Summary: Chronic Migraine

One double-blind, placebo-controlled, randomized trial has evaluated transnasal SPG blocks for chronic migraine. The trial found a significantly greater short-term (up to 24 hours) reduction in pain severity after active treatment versus placebo. However, there were no significant longer term effects on other outcomes (ie, 1 and 6 months after 12 treatments over 6 weeks). The trial was underpowered to detect outcomes at 1 and 6 months. It had some risks of bias due to a high rate of dropouts. Additional adequately powered trials are needed to determine the impact of SPG blocks on health outcomes.

Severe Acute Headache Treated in the Emergency Setting

Clinical Context and Therapy Purpose

The purpose of SPG block(s) in individuals who have severe acute headache treated in the emergency setting is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with severe acute headache treated in the emergency setting.

Interventions

The therapy being considered is a SPG block.

Comparators

The following therapy is currently being used to treat severe acute headache treated in the emergency setting: medication.

Outcomes

The general outcomes of interest are reductions in headache intensity and medication use.

Treatment-related adverse events are minor. Follow-up over several hours is needed to monitor for treatment effect.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- Due to a typically high placebo response rate in patients with headache, placebo-controlled trials were preferred.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

The published literature on SPG blocks to treat severe acute headache consists of a single double-blind, placebo-controlled, randomized trial, as reported by Schaffer et al (2015).¹¹ The trial included patients between the ages of 18 and 65 years who presented to the emergency department with a frontal-based crescendo-onset headache and a negative neurologic examination. The trial focused on frontal-based headaches because this population is considered most likely to respond to SPG blocks. Headaches were not classified into specific types but patients with sudden-onset headache were excluded. Ninety-three patients met eligibility criteria and were randomized 1:1 to treatment with bupivacaine 0.5% (n=45) or to a saline placebo (n=48) applied using the Tx360 device. The intervention consisted of 1 treatment session. The primary outcome was a 50% absolute pain reduction on a 100-mm visual analog scale (VAS) 15 minutes posttreatment. Four patients, 2 in each group, withdrew before receiving the intervention and 2 were deemed ineligible after randomization. Thus, 41 patients in the bupivacaine group and 46 in the placebo group were included in the primary analysis.

For the primary outcome, 20 (49%) patients in the bupivacaine group and 19 (41%) patients in the placebo group had at least a 50% reduction in the mean VAS score. The difference between groups (7.5%) did not differ statistically (95% confidence interval [CI], -13% to 27%). Secondary outcomes, including at least a 19-mm reduction in VAS score, percentage of patients who were headache-free 15 minutes postintervention, and percentage of patients who were nausea-free 15 minutes postintervention, also did not differ significantly between groups. Seventy-six (88%) patients were available for follow-up after 24 hours. The percentage of patients headache-free at 24 hours was significantly higher in the bupivacaine group (n=26 [72%]) than in the placebo group (n=19 [48%]; difference, 25%; 95% CI, 2.6% to 44%). No serious adverse events were reported in either group. The trialists stated that, in retrospect, outcome assessment at 1 hour after treatment would have been useful because headache relief at 1 hour, but not at 24 hours, is clinically relevant for emergency department headache patients.

Section Summary: Severe Acute Headache Treated in the Emergency Setting

One double-blind, placebo-controlled, randomized trial has evaluated a single transnasal SPG block for treating patients with acute headache presenting to an emergency department. The trialists did

not find a statistically significant benefit for active treatment compared with placebo 15 minutes postintervention. Significantly more patients were headache-free at 24 hours in the active treatment than in the placebo group, but, in the absence of short-term pain relief, SPG blocks would not be a clinically useful treatment in the emergency setting. Future studies conducted in the emergency setting should assess outcomes for an intermediate time period (eg, 1 or 2 hours posttreatment).

Cluster Headache

Clinical Context and Therapy Purpose

The purpose of SPG block(s) in individuals who have cluster headaches is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with cluster headache.

Interventions

The therapy being considered is a SPG block.

Comparators

The following therapies are currently being used to treat cluster headaches: medication and oxygen therapy.

Outcomes

The general outcomes of interest are reductions in headache frequency, intensity, and medication use. Treatment-related adverse events are minor. A series of injections may be given over several weeks, with follow-up over months to monitor for treatment effect and durability.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- Due to a typically high placebo response rate in patients with headache, placebo-controlled trials were preferred.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

No RCTs or nonrandomized controlled studies were identified that evaluated 1 of the 3 catheter devices commercially available in the United States for performing SPG blocks for treating cluster headache.

Case Series

Two case series in patients with chronic drug-resistant cluster headache were published by a research group in Italy.^{12,13} Both studies used a needle (20-gauge in 1 study, 18-gauge in the other) under endoscopic control to inject a mixture of local anesthetics and steroid as close as possible to the SPG. The mixture consisted of triamcinolone acetonide (40 mg), 1% bupivacaine (4 mL), and 2% mepivacaine with 1/100,000 adrenaline (2 mL).

Pipolo et al (2010) reported on 15 patients who received 3 SPG block treatments a mean of 3 days apart. Eight (53%) of the 15 patients experienced complete remission of cluster headache symptoms.¹² Three (20%) of these continued to be in remission at last follow-up (mean, 18 months). One (7%) patient experienced partial benefit and 6 (40%) reported either no benefit or a benefit for

less than 2 weeks. Three (20%) patients experienced complications, including 2 cases of severe epistaxis and 1 of reduced buccal opening that resolved after 5 months.

The earlier study by Felisati et al (2006), included 21 patients who received between 2 and 4 total treatment sessions, provided 1 week apart.¹³ Including 1 patient in whom the treatment could not be applied, 9 (45%) experienced no efficacy, 3 (15%) experienced a partial benefit, and 8 (40%) experienced a complete temporary benefit. In the 8 patients who had complete disappearance of attacks, the benefit lasted 2 to 4 weeks in 3 patients, 3 to 6 months in 3 patients, and 12 to 24 months in 2 patients. Four (19%) patients experienced treatment-related complications, which consisted of 1 case of marked nasal epistaxis 3 days after the procedure and 3 cases of temporary diplopia.

Section Summary: Cluster Headache

The literature includes 2 case series, both of which were published by the same research group in Italy. The approach to treatment was similar in both studies but differed in terms of medication and application technique currently used in the United States. It is unclear how the safety or efficacy of the procedure used in the case series differs from an intranasal SPG block applying local anesthetics and using a U.S. Food and Drug Administration cleared device. 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. These studies had small sample sizes and lacked a sham treatment or alternative therapy for treating cluster headache.

Postdural Puncture Headache

Clinical Context and Therapy Purpose

The purpose of SPG block(s) in individuals who have a postdural puncture headache (PDPH) is to provide a treatment option that is an alternative to or an improvement on existing therapies. The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with PDPH.

Interventions

The therapy being considered is a SPG block.

Comparators

The following therapies are currently being used to treat PDPH: conservative therapy (eg, bed rest, oral or intravenous hydration), medication (eg, analgesics, caffeine, antiemetics), and epidural blood patch. Epidural blood patch is considered the definitive treatment for PDPH.^{14,15,16}

Outcomes

The general outcomes of interest are reduction in headache intensity and duration, medication use, and avoidance of epidural blood patch use.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- Due to a typically high placebo response rate in patients with headache, placebo-controlled trials were preferred.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Dwivedi et al (2023) published a systematic review and meta-analysis of 9 RCTs comparing SPG block to other treatments in patients with PDPH.¹⁷ The SPG blocks consisted of various lidocaine concentrations (2% to 10%) with some studies combining lidocaine with ropivacaine, dexamethasone, or epinephrine. Comparators included sham block with saline, intranasal lidocaine block, greater occipital nerve block, or pharmacotherapy. Six studies were considered to have "some concern" for bias while the remaining 3 had a low risk of bias. Efficacy outcomes included pain at various time points from 30 minutes up to 7 days after intervention. Tables 1 through 3 summarize the included studies, characteristics, and results of the meta-analysis, respectively. Limitations of the of the studies include the variety of anesthetic strengths and combinations used for SPG, the open-label design of the majority of the studies, and the small sample sizes.

Table 1. Comparison of Trials/Studies Included in the Systematic Review/Meta-Analysis

Study	Dwivedi et al (2023) ¹⁷
Abotaleb et al (2022)	●
Bohara et al (2022)	●
Jespersen et al (2020)	●
Kumar et al (2021)	●
Mowafi et al (2021)	●
Nazir et al (2021)	●
Puthenveetil et al (2018)	●
Yilmaz et al (2020)	●
Youssef et al (2021)	●

Table 2. Systematic Review & Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Dwivedi et al (2023) ¹⁷	Through Oct 2022	9	Pts with PDPH treated with SPG block vs placebo or other intervention	381 (20-100)	RCT	Up to 7 days after intervention

PDPH: postdural puncture headache; RCT: randomized controlled trial; SPG: sphenopalatine ganglion.

Table 3. Systematic Review & Meta-Analysis Results

Study	Pain at 30 Minutes	Pain at 2 Hours	Pain at 24 Hours	Treatment Failure
Dwivedi et al (2023) ¹⁷				
Total N	271	211	251	293
Pooled effect (95% CI)	SMD: -1.99 (-3.88 to -0.10)	SMD: -1.23 (-3.06 to 0.59)	SMD: -0.40 (-0.85 to 0.06)	RR: 0.40 (0.18 to 0.91)
P (p)	97% (<.00001)	97% (<.00001)	63% (NR)	66% (NR)

CI: confidence interval; NR: not reported; RR: risk ratio; SMD: standardized mean difference.

Section Summary: Postdural Puncture Headache

One systematic review of 9 RCTs (N=381) compared SPG blocks to various PDPH treatments or sham. The SPG blocks consisted of various lidocaine concentrations (2% to 10%) with some studies combining lidocaine with ropivacaine, dexamethasone, or epinephrine. The primary outcome was the pooled assessment of the pain at various intervals. SPG blocks significantly improved pain compared with controls at 30 minutes, 1 hour, and 4 hours, but not at 2 hours, 6 hours, 8 hours, 12 hours, or 24 hours. The use of rescue treatment was similar between groups. Limitations of the analysis include the variety of anesthetic strengths and combinations used for SPG, the open-label design of the majority of the studies, and the small sample size of the studies.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.¹⁸ 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 onabotulinumtoxin A.

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.¹⁹ Sphenopalatine ganglion stimulation is rated as a Level B (probably effective) acute treatment recommendation. However, the recommendation for sphenopalatine ganglion stimulation was based on a single randomized controlled trial that evaluated an implanted, on-demand, acute electrical stimulation device of the SPG,²⁰ 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 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03337620 ^a	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	180	Mar 2024 (recruiting)
NCT03984045	Sphenopalatine Ganglion Block for Treating Acute Frontal Migraine Headache in Pediatric Patients	72	Dec 2022
NCT04069897	Botulinum Toxin Type A Blockade of the Sphenopalatine Ganglion in Treatment-refractory Chronic Migraine (MiBlock)	170	Dec 2024
NCT03944876	Botulinum Toxin Type A Blockade of the Sphenopalatine Ganglion in Treatment-refractory Chronic Cluster Headache (BASIC)	112	Sep 2025
<i>Unpublished</i>			
NCT04255420	Sphenopalatine Ganglion Blocks for Headaches in the Emergency Department	84	Jun 2021 (unknown)

NCT: national clinical trial.

^a Denotes industry-sponsored or -cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	64400	Injection, anesthetic agent; trigeminal nerve, any division or branch
	64505	Injection, anesthetic agent; sphenopalatine ganglion
	64999	Unlisted procedure, nervous system
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/01/2017	BCBSA Medical Policy adoption
08/01/2018	Policy revision without position change
01/01/2019	Policy revision without position change
02/01/2024	Policy reactivated. Previously archived from 04/01/2020 to 01/31/2024.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent

with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	AFTER <u>Blue font: Verbiage Changes/Additions</u>
Reactivated Policy Policy Statement: N/A	Sphenopalatine Ganglion Block for Headache 7.01.159 Policy Statement: <ul style="list-style-type: none">I. Sphenopalatine ganglion blocks are considered investigational for all headache indications, including but not limited to the treatment of migraines and non-migraine headaches.