PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY – 7.01.159

Sphenopalatine Ganglion Block for Headache

BCBSA Ref. Policy:	7.01.159	
Effective Date:	Feb. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Jan. 13, 2025	7.01.125 Occipital Nerve Stimulation
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

The sphenopalatine ganglion (SPG) is a group of nerve cells behind the nose. This nerve bundle is linked to the trigeminal nerve, which has three branches going to the eye area and the upper and lower jaws. The trigeminal nerve is the main nerve linked to headache disorders. A new type of treatment has been proposed to address headaches and facial pain. In this treatment, a hollow tube (a catheter) is inserted into the nose and maneuvered near the SPG. Once the catheter is in place, topical anesthesia is applied. The goal is to use the anesthesia as a way to block pain signals. This treatment is unproven (investigational). Larger, high-quality studies are needed to determine how effective this treatment is in the long term and how it compares to standard treatment for severe acute, migraine, and cluster headaches.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

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

Coding

Code	Description
CPT	
64999	Unlisted procedure, nervous system

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

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 US Food and Drug Administration (FDA) are available for the SPG blocking procedure.

Background

Headaches and Headache Treatments

Headaches are common neurologic disorders and are among the top reasons why individuals 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 two most common types of headache are migraines and tension-type headaches.

Migraines are the second-most common headache disorder, with a one-year migraine prevalence of approximately 12% in the United States (US).[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 three months, with features of migraine on at least eight days per month.[3]

Tension-type 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; lasting between 30 minutes and 7 days; and not accompanied by nausea, vomiting, photophobia, or phonophobia.[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).[3]

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. Individuals 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 individuals.[4] 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.[5] The reported incidence of PDPH as a complication of lumbar puncture is variable, ranging from 10% to 40% of lumbar puncture procedures.[5] Incidence may be as low as 2% when small gauge, non-cutting needles are used.

Treatment

A variety of medications are used to treat acute migraine episodes. They include medications taken at the onset to abort the attack (e.g., triptans, ergotamines, lasmiditan, calcitonin-gene related peptide antagonists) 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 two days per week. Botulinum toxin type A injections are an 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 (e.g., 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, individuals may seek emergency treatment. Tension-type headaches are generally treated with over-the-counter pain medication.

Sphenopalatine Ganglion Block

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 an intranasal 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 US,[6] but these treatments are not cleared or approved by the FDA.

Three catheter devices are commercially available in the US 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 two of the three commercially available catheters (the SpenoCath, Allevio), individuals are positioned on their back with their nose pointed vertically and their head turned to the side. With the Tx360 device, individuals remain seated.[7]

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.[7] A randomized controlled trial has described a course of treatment for migraines consisting of SPG blocks twice a week for six weeks (total, 12 treatments).

SPG blocks are proposed for both short-term and long-term treatment of headaches and migraines. When used in the emergency setting in individuals with severe acute headaches, the goal of treatment is to abort the current headache while the individual is in the emergency department. In the randomized controlled trial that provided a six-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 one and six months after the course of treatment.

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. The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The randomized trial evaluated a regimen of 12 SPG blocks over six 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 (i.e., one and six 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. The 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 individuals 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 an 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. The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two small case series, both of which evaluate an approach for intranasal SPG blocks that differ from the intervention currently available in the US, were identified. In these series, 40% to 50% of individuals 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 FDA. 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.

For individuals who have postdural puncture headache (PDPH) who receive SPG block(s), the evidence includes a systematic review of 9 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review included 9 RCTs (N=381) comparing 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. Additional studies, preferably RCTs with larger sample sizes, are needed to evaluate SPG blocks for treating PDPH. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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
NCT05213065	Efficacy of Transnasal Sphenopalatine Ganglion Block Using TX360® Device for Children and Adolescents With Chronic Daily Headaches: A Single Center, Prospective, Randomized, Double Blind, Placebo-controlled Study Assessing the Efficacy of the Transnasal Sphenopalatine Ganglion Block in the Treatment of Chronic Daily Headache in Children and Adolescents	120	Dec 2024
Unpublished			
NCT04255420	Sphenopalatine Ganglion Blocks for Headaches in the Emergency Department	84	Jun 2021 (unknown)
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	174	Dec 2023 (recruiting)
NCT03984045	Sphenopalatine Ganglion Block for Treating Acute Frontal Migraine Headache in Pediatric Patients	72	Dec 2022 (unknown)

NCT: national clinical trial

a Denotes industry-sponsored or -cosponsored trial.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion in 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] SPG 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.[19] SPG stimulation is rated as a Level B (probably effective) acute treatment recommendation. However, the recommendation for SPG stimulation was based on one 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.

Multi-society International Working Group

A multi-society international working group with U.S representation published clinical practice guidelines on postdural puncture headache (PDPH) management.[21,] The guidelines state that "Evidence does not support routine use of SPGBs [sphenopalatine ganglion blocks) to treat PDPH". This was a Grade I level recommendation with a low level of certainty.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

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

References

1. International Association for the Study of Pain (IASP). Global year against headache. **https://www.iasp-pain.org/advocacy/global-year/headache/**. Accessed December 12, 2024.
2. Singh A, Soares WE. Management strategies for acute headache in the emergency department. Emerg Med Pract. Jun 2012; 14(6): 1-23; quiz 23-4. PMID 22830180
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. Jan 2018; 38(1): 1-211. PMID 29368949
4. Berger CW, Crosby ET, Grodecki W. North American survey of the management of dural puncture occurring during labour epidural analgesia. Can J Anaesth. Feb 1998; 45(2): 110-4. PMID 9512843
5. Plewa MC, McAllister RK. Postdural Puncture Headache (PDPH). In: StatPearls. Treasure Island (FL): StatPearls Publishing; August 23, 2020. PMID 28613675
6. Sanders M, Zuurmond WW. Efficacy of sphenopalatine ganglion blockade in 66 patients suffering from cluster headache: a 12- to 70-month follow-up evaluation. J Neurosurg. Dec 1997; 87(6): 876-80. PMID 9384398
7. American Migraine Foundation. Sphenopalatine Ganglion Blocks in Headache Disorders. 2016; **https://americanmigrainefoundation.org/resource-library/sphenopalatine-ganglion-blocks/**. Accessed December 12, 2024.
8. Cady R, Saper J, Dexter K, et al. A double-blind, placebo-controlled study of repetitive transnasal sphenopalatine ganglion blockade with tx360(®) as acute treatment for chronic migraine. Headache. Jan 2015; 55(1): 101-16. PMID 25338927
9. Cady RK, Saper J, Dexter K, et al. Long-term efficacy of a double-blind, placebo-controlled, randomized study for repetitive sphenopalatine blockade with bupivacaine vs. saline with the Tx360 device for treatment of chronic migraine. Headache. Apr 2015; 55(4): 529-42. PMID 25828648

10. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 2nd edition. Cephalalgia. 2004; 24 Suppl 1: 9-160. PMID 14979299

11. Schaffer JT, Hunter BR, Ball KM, et al. Noninvasive sphenopalatine ganglion block for acute headache in the emergency department: a randomized placebo-controlled trial. Ann Emerg Med. May 2015; 65(5): 503-10. PMID 25577713

12. Pipolo C, Bussone G, Leone M, et al. Sphenopalatine endoscopic ganglion block in cluster headache: a reevaluation of the procedure after 5 years. Neurol Sci. Jun 2010; 31 Suppl 1: S197-9. PMID 20464621

13. Felisati G, Arnone F, Lozza P, et al. Sphenopalatine endoscopic ganglion block: a revision of a traditional technique for cluster headache. Laryngoscope. Aug 2006; 116(8): 1447-50. PMID 16885751

14. Seebacher J, Ribeiro V, LeGuillou JL, et al. Epidural blood patch in the treatment of post dural puncture headache: a double blind study. Headache. Nov 1989; 29(10): 630-2. PMID 2693404

15. Sandesc D, Lupei MI, Sirbu C, et al. Conventional treatment or epidural blood patch for the treatment of different etiologies of post dural puncture headache. Acta Anaesthesiol Belg. 2005; 56(3): 265-9. PMID 16265829

16. van Kooten F, Oedit R, Bakker SL, et al. Epidural blood patch in post dural puncture headache: a randomised, observer-blind, controlled clinical trial. J Neurol Neurosurg Psychiatry. May 2008; 79(5): 553-8. PMID 17635971

17. Dwivedi P, Singh P, Patel TK, et al. Trans-nasal sphenopalatine ganglion block for post-dural puncture headache management: a meta-analysis of randomized trials. Braz J Anesthesiol. 2023; 73(6): 782-793. PMID 37422191

18. Barad M, Ailani J, Hakim SM, et al. Percutaneous Interventional Strategies for Migraine Prevention: A Systematic Review and Practice Guideline. Pain Med. Jan 03 2022; 23(1): 164-188. PMID 34382092

19. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. Headache. Jul 2016; 56(7): 1093-106. PMID 27432623

20. Schoenen J, Jensen RH, Lantéri-Minet M, et al. Stimulation of the sphenopalatine ganglion (SPG) for cluster headache treatment. Pathway CH-1: a randomized, sham-controlled study. Cephalalgia. Jul 2013; 33(10): 816-30. PMID 23314784

21. Uppal V, Russell R, Sondekoppam RV, et al. Evidence-based clinical practice guidelines on postdural puncture headache: a consensus report from a multisociety international working group. Reg Anesth Pain Med. Jul 08 2024; 49(7): 471-501. PMID 37582578

History

Date	Comments
08/01/17	New Policy, approved July 18, 2017, add to Surgery section. Policy created with literature review through March 23, 2017. Sphenopalatine ganglion blocks are considered investigational for all indications, including but not limited to the treatment of migraines and non-migraine headaches.
09/12/18	Coding update, added CPT code 64505.
10/05/18	Coding update, removed CPT code 64505.

Date	Comments
12/01/18	Annual Review, approved November 21, 2018. Policy updated with literature review through September 2018; no references were added. Policy statement unchanged.
02/01/19	Annual Review, approved January 22, 2019. Policy updated with literature review through September 2018; no references were added. Policy statement unchanged.
02/01/20	Annual Review, approved January 9, 2020. Policy updated with literature review through September 2019; no references added. Policy statement unchanged.
02/01/21	Annual Review, approved January 6, 2021. Policy updated with literature review through August 20, 2020; references added. Indication added for individuals with postdural puncture headache. Policy statement unchanged.
02/01/22	Annual Review, approved January 10, 2022. Policy updated with literature review through October 1, 2021; references added. Policy statement unchanged.
02/01/23	Annual Review, approved January 9, 2023. Policy updated with literature review through September 13, 2022; no references added. Minor editorial refinement to policy statement; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
02/01/24	Annual Review, approved January 8, 2024. Policy updated with literature review through September 25, 2023; references added. Policy statement unchanged.
02/01/25	Annual Review, approved January 13, 2025. Policy updated with literature review through October 7, 2024; reference added. Policy statement unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.