

MEDICAL POLICY

POLICY TITLE	SPHENOPALATINE GANGLION BLOCK FOR HEADACHE
POLICY NUMBER	MP 4.046

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	9/1/2024

[POLICY RATIONALE](#)
[DISCLAIMER](#)
[POLICY HISTORY](#)

[PRODUCT VARIATIONS](#)
[DEFINITIONS](#)
[CODING INFORMATION](#)

[DESCRIPTION/BACKGROUND](#)
[BENEFIT VARIATIONS](#)
[REFERENCES](#)

I. POLICY

Sphenopalatine ganglion blocks are considered **investigational** for all headache indications, including but not limited to the treatment of migraines and non-migraine headaches, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP 2.064 Biofeedback and Neurofeedback Therapy
MP 2.372 Occipital Nerve Stimulation
MP 6.020 Transcutaneous Electrical Nerve Stimulation

II. PRODUCT VARIATIONS

[TOP](#)

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

III. DESCRIPTION/BACKGROUND

[TOP](#)

Chronic migraine and severe headaches are common conditions, and the available treatments are not universally effective. A proposed treatment option is blocking the sphenopalatine

MEDICAL POLICY

POLICY TITLE	SPHENOPALATINE GANGLION BLOCK FOR HEADACHE
POLICY NUMBER	MP 4.046

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.

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. Migraines 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.

Tension headaches have a prevalence of approximately 40%. Diagnostic criteria include the presence of at least two of the following four characteristics: bilateral headache location, non-pulsating 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 (e.g., rhinorrhea, eyelid edema, or drooping).

Post dural 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. They include medications taken at the onset of an attack to abort the attack (triptans, ergotamines, lasmiditan, calcitonin-gene related peptide antagonists) and medications to treat the pain and other symptoms of migraines once they are established (e.g., 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-

MEDICAL POLICY

POLICY TITLE	SPHENOPALATINE GANGLION BLOCK FOR HEADACHE
POLICY NUMBER	MP 4.046

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, 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 (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, but these treatments are not cleared or approved by 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® Nerve Block Catheter), 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 (RCT) 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

MEDICAL POLICY

POLICY TITLE	SPHENOPALATINE GANGLION BLOCK FOR HEADACHE
POLICY NUMBER	MP 4.046

headaches, the goal of treatment is to abort the current headache while the patient is in the emergency department. In the RCT 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.

REGULATORY STATUS

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

IV. RATIONALE

[TOP](#)

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 longer term effects (i.e., 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 a single 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 evaluate an approach for intranasal SPG blocks that differs from the intervention currently available in the United States,

MEDICAL POLICY

POLICY TITLE	SPHENOPALATINE GANGLION BLOCK FOR HEADACHE
POLICY NUMBER	MP 4.046

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 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.

V. DEFINITIONS

[TOP](#)

N/A

VI. BENEFIT VARIATIONS

[TOP](#)

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

[TOP](#)

Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical

MEDICAL POLICY

POLICY TITLE	SPHENOPALATINE GANGLION BLOCK FOR HEADACHE
POLICY NUMBER	MP 4.046

policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

[TOP](#)

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

Procedure Codes							
64400	64505	64999					

IX. REFERENCES

[TOP](#)

1. International Association for the Study of Pain (IASP). Global year against headache.
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
8. Cady R, Saper J, Dexter K, et al. A double-blind, placebo-controlled study of repetitive transnasal sphenopalatine ganglion blockade with tx360((R)) 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

MEDICAL POLICY

POLICY TITLE	SPHENOPALATINE GANGLION BLOCK FOR HEADACHE
POLICY NUMBER	MP 4.046

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.* Jul 06 2023. 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, Lanteri-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
21. Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.159, Sphenopalatine Ganglion Block for Headache. December 2023

X. POLICY HISTORY

[TOP](#)

MP 4.046	06/17/2020 Consensus Review. Policy statement unchanged. Product variation, Background, Benefit variation, Disclaimer, and coding updated. References reviewed.
	04/20/2021 Consensus Review. Policy statement unchanged. Background updated to include addition of postdural puncture headache. References updated.
	02/22/2022 Consensus Review. No change in policy statement. Product Variation updated and revised FEP language added. Background amended. Referenced added.

MEDICAL POLICY

POLICY TITLE	SPHENOPALATINE GANGLION BLOCK FOR HEADACHE
POLICY NUMBER	MP 4.046

	06/02/2023 Consensus Review. No change to policy statement. Title changed to Sphenopalatine Ganglion Block for Headache. Background and References updated.
	06/03/2024 Consensus Review. No change to policy statement. Background and Rationale updated. Reference added.

[TOP](#)

Health care benefit programs issued or administered by Capital Blue Cross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company®, and Keystone Health Plan® Central. Independent licensees of the Blue Cross BlueShield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.