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Medical Policy Sphenopalatine Ganglion Block for Headache

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Policy Number: 026

Authorization Information

BCBSA Reference Number: 7.01.159 (For Plans internal use only) NCD/LCD: N/A

Related Policies

- Transcutaneous Electrical Nerve Stimulation, #003
- Biofeedback as a Treatment of Headache, #210
- Botulinum Toxin Injection for Muscle and Nerve Conditions, #006
- Occipital Nerve Stimulation, #237
- Surgical Deactivation of Headache Trigger Sites, #801

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

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

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO Blue sm	This is not a covered service.
Medicare PPO Blue SM	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this procedure.

DESCRIPTION

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,} Migraines 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 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-type headaches have a prevalence of approximately 40%.2, 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.^{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 (eg, 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. 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.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.

A variety of medications are used to treat acute migraine episodes. These 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 (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-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 an intranasal 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,^{6,} 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 Spheno Cath®, 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.^{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 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.

Summary

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.

Summary of Evidence

For individuals who have chronic migraine who receive sphenopalatine ganglion (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 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 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.

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.

Date	Action
1/2025	Annual policy review. References updated. Policy statements unchanged.
1/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2023	Annual policy review. Minor editorial refinement to policy statement; intent unchanged.
1/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.

Policy History

1/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2017	New medical policy describing investigational indications. Effective 10/1/2017.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information: <u>Medical Policy Terms of Use</u> <u>Managed Care Guidelines</u> <u>Indemnity/PPO Guidelines</u> <u>Clinical Exception Process</u> <u>Medical Technology Assessment Guidelines</u>

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