Corporate Medical Policy

Sphenopalatine Ganglion Block for Headache

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Description of Procedure or Service

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 an intranasal topical anesthetic. Several catheters approved by the U.S. Food and Drug Administration (FDA) are available for the SPG blocking procedure.

HEADACHES AND HEADACHE TREATMENTS

Headaches are common neurologic disorders and are among the top reasons that 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 tension-type headaches and migraines. Diagnostic criteria for tension headaches include the presence of at least two of the following characteristics: bilateral headache location, non-pulsating pain, mild-to-moderate intensity, and headache not aggravated by physical activity.

Migraines are the second-most common headache disorder. 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 migraines are defined as attacks at least 15 days per month for more than 3 months, with features of migraine at least 8 days per month.

Cluster headaches are less common than tension or migraine headaches. 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 (eg, relaxation, cognitive therapy) are used to manage migraine headache. Botulinum toxin type A injections are an FDA–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 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 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, reaching the SPG. Some form of SPG blocking procedure has been used for many years. 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. Another variation was to insert a needle into the cheek and inject local anesthetic but this no longer appears to be used because it is more invasive and painful. 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 that contain local anesthetic. The catheters are inserted intranasally and, once in place, the local anesthetic is applied through the catheter. With 2 of the 3 commercially available catheters (the SpenoCath®, Allevio™), patients are positioned on their back with their nose pointed vertically and their head turned to the side. With the Tx360® device, patients remain seated.

The company marketing the Tx360® device proposes its use in the context of the MiRx™ protocol. 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. 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).

SPG 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 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 (JET Medical), and the SpenoCath® (Dolor Technologies) are considered class I devices by the U.S. Food and Drug Administration (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 local anesthetic intranasally.

RELATED POLICIES
TENS (Transcutaneous Electrical Nerve Stimulator)
Botulinum Toxin Injection

Sphenopalatine Ganglion Block for Headache

Occipital Nerve Stimulation
Surgical Deactivation of Headache Trigger Sites

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Sphenopalatine ganglion blocks are considered investigational for all indications, including but not limited to the treatment of migraines and non-migraine headaches. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Sphenopalatine Ganglion Block for Headache is covered

Not applicable.

When Sphenopalatine Ganglion Block for Headache is not covered

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

Policy Guidelines

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 twelve 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 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 the effects of the technology on health outcomes.

For individuals who have severe acute headache treated in the emergency setting who receive SPG block(s), the evidence includes one 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 post-intervention). The trialists did not collect pain data again until 24 hours post-treatment, 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 the effects of the technology on health outcomes.

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, 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 Food and Drug Administration. Additional studies, preferably RCTs, are needed to evaluate SPG blocks for treating cluster headaches. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

This procedure is sometimes reported with code 64505, but, in the absence of an actual injection, that code is incorrect. The American Medical Association recommends using an unlisted code 64999 to report this procedure.

It was mentioned that this service is reported by some providers with code 64505 along with the code for trigeminal block 64400.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.159, 5/8/2017

Specialty Matched Consultant Advisory Panel 10/2017

Specialty Matched Consultant Advisory Panel 10/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.159, 11/8/2018

Policy Implementation/Update Information

7/28/17	New policy developed. Sphenopalatine ganglion blocks are considered investigational for all indications, including but not limited to the treatment of migraines and non-migraine headaches. (sk)
8/24/18	Specialty Matched Consultant Advisory Panel review 10/25/2017. (sk)
11/9/18	Specialty Matched Consultant Advisory Panel review 10/24/2018. (sk)
1/29/19	Reference added. Biofeedback removed from list of Related Policies. (sk)