MEDICAL POLICY – 7.01.159
Sphenopalatine Ganglion Block for Headache

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, 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**

<table>
<thead>
<tr>
<th>Procedure</th>
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<tr>
<td>Sphenopalatine ganglion blocks</td>
<td>Sphenopalatine ganglion blocks are considered investigational for all indications, including but not limited to the treatment of migraines and non-migraine headaches.</td>
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### Coding

<table>
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### 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) by accessing it intranasally and applying topical anesthetic to it. Several catheters approved by the Food and Drug Administration are available for the SPG blocking procedure.
Background

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 two most common types of headache are tension-type headaches and migraines. Tension headaches have a prevalence of approximately 40%. Diagnostic criteria include the presence of at least 2 of the following characteristics: bilateral headache location, nonpulsating pain, mild-to-moderate intensity, and headache not aggravated by physical activity. Migraines are the second-most common headache disorder, with a 1-year migraine prevalence of approximately 12% in the United States. They 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.

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 (eg, 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 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 intranasally insert 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. 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 is 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 can be 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. 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).

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 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.

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 longer 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 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 1 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 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 differ 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 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
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<th>Trial Name</th>
<th>Planned Enrollment</th>
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<td>Study Evaluating Sphenopalatine Ganglion Block (SPGB) for Treatment of Postdural Puncture Headache (PDPH)</td>
<td>30</td>
<td>Dec 2017</td>
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<tr>
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<td>Study Evaluating Sphenopalatine Ganglion Block (SPGB) for Treatment of Postdural Puncture Headache (PDPH)</td>
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<td>Dec 2017</td>
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<td>NCT02090998</td>
<td>Sphenopalatine Ganglion Nerve Block vs. Elavil for Treatment of Transformed Migraines</td>
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<td>May 2018</td>
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NCT: national clinical trial.

Practice Guidelines and Position Statements

No guidelines or statements were identified.
Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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 numbing medication intranasally.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>08/01/17</td>
<td>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.</td>
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</table>

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