

# Protocol

## Sphenopalatine Ganglion Block for Headache

(701159)

<b>Medical Benefit</b>		<b>Effective Date:</b> 12/01/19	<b>Next Review Date:</b> 09/20
<b>Preauthorization</b>	No	<b>Review Dates:</b> 09/19	

***This Protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"><li>• With chronic migraine headache</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Sphenopalatine ganglion block(s)</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Medication</li><li>• Self-management (e.g., relaxation, exercise)</li><li>• Botulinum toxin injection</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Quality of life</li><li>• Treatment-related morbidity</li></ul>
Individuals: <ul style="list-style-type: none"><li>• With acute headache treated in the emergency setting</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Sphenopalatine ganglion block(s)</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Medication</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Quality of life</li><li>• Treatment-related morbidity</li></ul>
Individuals: <ul style="list-style-type: none"><li>• With cluster headache</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Sphenopalatine ganglion block(s)</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Medication</li><li>• Oxygen therapy</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Quality of life</li><li>• Treatment-related morbidity</li></ul>

### 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 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 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 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 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 the effects of the technology on health outcomes.

## POLICY

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

## BACKGROUND

### 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>

Tension headaches have a prevalence of approximately 40%.<sup>2</sup> 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.<sup>3</sup>

Cluster headaches are less common than tension or migraine headaches, with an estimated prevalence of 0.1% of the population.<sup>2</sup> 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 two days per week. In addition to medication, behavioral treatments (e.g., 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 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 radio-frequency lesioning have been used outside of the United States,<sup>4</sup> but these treatments are not cleared or approved by the U.S. Food and Drug Administration.

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 two of the three commercially available catheters (the SpenoCath<sup>®</sup>, Allevio<sup>™</sup>), patients are positioned on their back with their nose pointed vertically and their head turned to the side. With the Tx360<sup>®</sup> device, patients remain seated.<sup>5</sup>

The company marketing the Tx360<sup>®</sup> device proposes its use in the context of the MiRx<sup>™</sup> protocol.<sup>6</sup> This two 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.<sup>5</sup> 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).

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 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.

## REGULATORY STATUS

The Tx360<sup>®</sup> Nasal Applicator (Tian Medical), the Allevio<sup>™</sup> SPG Nerve Block Catheter (JET Medical), and the SpenoCath<sup>®</sup> (Dolor Technologies) are considered class I devices by the Food and Drug Administration and are exempt from 510(k) requirements. This classification does not require submission of clinical data on efficacy but only notification of Food and Drug Administration prior to marketing. All three devices are used to apply numbing medication intranasally.

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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