

DRAFT Medical Coverage Policy | Sphenopalatine Ganglion Block for Headache



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OVERVIEW

Chronic migraine and severe headaches are common conditions and currently available treatments are not universally effective. A proposed treatment option is blocking the sphenopalatine ganglion (SPG) nerve by applying topical anesthetic medication intranasally. Several catheters approved by the Food and Drug Administration are available for the SPG blocking procedure.

MEDICAL CRITERIA

Not applicable.

PRIOR AUTHORIZATION

Not applicable.

POLICY STATEMENT

Sphenopalatine ganglion blocks are considered not medically necessary for all indications, including but not limited to the treatment of migraines and non-migraine headaches as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND

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.¹ The 2 most common types of headache are tension-type headaches and migraines. Tension-headaches have a prevalence of approximately 40%.² They are diagnosed when patients report at least 2 of the following characteristics: bilateral headache location, nonpulsating pain, mild to moderate intensity and headache not aggravated by physical activity.³ Migraines are the second-most common headache disorder with 1-year prevalence of migraine in the United States of approximately 12%.² They are characterized by severe pain on 1 or both sides of the head, an upset stomach, and, at times, disturbed vision. Migraines can be categorized by headache frequency. According to the Third Edition of the International Headache Classification (ICHD-3), migraine without aura (previously known as common migraine) is defined as at least 5 attacks per month meeting other diagnostic criteria.³ 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.² Cluster headaches 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 such as rhinorrhea and eyelid edema or drooping. Due to the severity of pain associated with cluster headaches, patients may seek emergency treatment.

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, narcotic analgesics, 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 such as relaxation and cognitive therapy are used in the management of migraine headache. Moreover, botulinum toxin type A injections are a U.S. Food and Drug Administration (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. Tension-type headaches are generally treated with over the counter pain medication.

Sphenopalatine Ganglion Block

Sphenopalatine ganglion (SPG) nerve blocks are a proposed treatment option for chronic migraines and some severe non□ migraine headaches. The SPG is a group of nerve cells that is 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 nerve 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 currently proposed procedure for SPG nerve blockade is to insert a catheter intranasally that is attached to a syringe carrying local anesthetic (eg, lidocaine or 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 since it is more invasive and can be painful.

Neurostimulation of the SGB and SGB blockade with radiofrequency lesioning have been used outside of the United States but these treatments are not FDA-cleared or approved.

Three catheter devices are currently 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® or 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.⁴ The company marketing the Tx360® device is proposing its use in the context of a protocol called the MiRx™ protocol.⁵ 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 states that the procedure can be repeated as often as needed to control pain.⁴ An RCT described a course of treatment for migraines consisting of SPG blocks twice a week for 6 weeks (total of 12 treatments)

For individuals who have chronic migraine who receive sphenopalatine ganglion blocks, the evidence includes 1 RCT and a case report. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCT was double-blind and placebo controlled, and provided a course of 12 SPG blocks over 6 weeks. It found significantly greater short-term (up to 24 hours) benefits of active treatment versus placebo. There were not significant longer-term effects (ie, 1 and 6 months after a course of

12 treatments). The study was underpowered to detect longer term efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have severe acute headache treated in an emergency setting who receive sphenopalatine ganglion blocks, the evidence includes 1 RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCT was double-blind and placebo controlled, and provided a single SPG block. There was not a statistically significant difference between active treatment and placebo in the primary outcome, pain reduction 15 minutes postintervention. The study did not collect pain data again while patients were in the emergency department (eg, at 1 hour after treatment). At 24 hours after treatment, significantly more patients were headache-free in the active treatment versus placebo group. However, there is insufficient evidence that 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 sphenopalatine ganglion blocks, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two small case series were available; the approach to intranasal SPG blocks differed from the intervention currently available in the United States. It is not clear how the safety or efficacy of the procedure used in the case series differs from an intranasal SPG block applying local anesthetics and using an FDA cleared device. In the series, 40-50% of patients experienced complete symptom relief for a variable length of time and about 20% had treatment-related complications. 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.

CODING

It has been mentioned that this procedure is sometimes reported with CPT code 64505 – Injection, anesthetic agent; sphenopalatine ganglion – but it is felt that in the absence of an actual injection, that code is incorrect. The American Medical Association recommends using an unlisted code 64999, Unlisted procedure, nervous system – to report this procedure.

RELATED POLICIES

None

PUBLISHED

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