

## ***Sphenopalatine Ganglion Block for Headache and Pain***

**Effective:** February 1, 2019

**Next Review:** May 2019

**Last Review:** January 2019

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

The sphenopalatine ganglion (SPG) is a group of nerve cells located behind the bony structures of the nose. SPG blocks may be used to treat headaches and other forms of pain with local anesthetics in low concentrations which can block the sensory fibers and thereby reduce pain while maintaining function.

### **MEDICAL POLICY CRITERIA**

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

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### **CROSS REFERENCES**

1. [Occipital Nerve Stimulation](#), Surgery, Policy No. 174

## BACKGROUND

### SPHENOPALATINE GANGLION BLOCK

Sphenopalatine ganglion (SPG) nerve blocks are a proposed treatment option for chronic migraines, some severe non-migraine headaches, and non-headache pain. 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 (e.g., 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. 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.

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 two of the three 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.<sup>[1]</sup>

The company marketing the Tx360® device is proposing its use in the context of a protocol called the MiRx™ protocol.<sup>[2]</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 several 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. <sup>[1]</sup> An RCT described a course of treatment for migraines consisting of SPG blocks twice a week for six weeks (total of 12 treatments).

### REGULATORY STATUS

The Tx360® Nasal Applicator (Tian Medical), Allevio™ SPG Nerve Block Catheter (JET Medical), and 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 regarding efficacy but only notification of FDA prior to marketing. These three devices are all used to apply numbing medication intranasally.

## EVIDENCE SUMMARY

The objective of this evidence review is to evaluate whether SPG blocks improve health outcomes in patients with headaches and other pain compared with other accepted standards of practice. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition. Because the placebo response rate is typically high in patients with headache and pain, the assessment of evidence is mainly focused on randomized, placebo-controlled trials.

### CHRONIC MIGRAINE

One double-blind placebo-controlled RCT was published in two 2015 publications by Cady. The first publication<sup>[3]</sup> reported on the primary outcome measure and key secondary outcomes, and the subsequent publication<sup>[4]</sup> reported on supplemental secondary outcomes and longer term follow-up. The trial included patients who met International Classification of Headache Disorders (ICHD-2) diagnostic criteria for chronic migraine headache<sup>[5]</sup> and had CM for at least three months. Patients could use concomitant headache medication, but needed to agree not to make changes in medication use during the study period. Following an initial 28-day baseline period to confirm the diagnosis of CM, patients were randomized 2:1 to receive treatment with 0.5% bupivacaine or saline (placebo) applied using the Tx360® device. Patients received a series of 12 treatments, two treatments a week for six weeks. The primary outcome was change in pain severity, measured by a 0 to 10 numeric rating scale (NRS). Pain severity was assessed 15 minutes, 30 minutes and 24 hours after each treatment. Key secondary outcome measures were the Patient's Global Impression of Change (PGIC), the Headache Impact Test (HIT-6) questionnaire and patient satisfaction with treatment. In addition, patients kept headache diaries throughout the study.

Forty-one patients met eligibility criteria and had CM diagnoses confirmed during the baseline period. These patients were randomized to receive application of bupivacaine (n=27) or placebo (n=13). One patient in the placebo group withdrew consent, and three patients were excluded from analysis due to protocol violations, leaving 38 patients in the final dataset. This included 26 in the bupivacaine group and 12 in the placebo group. Mean baseline scores on the NRS were 4.8 in the bupivacaine group and 4.5 in the placebo group. When pooling findings for all treatments, patients in the bupivacaine group reported a significantly greater reduction in the NRS than the placebo group at 15 minutes, 30 minutes, and 24 hours after treatment. An analysis also found significantly lower PGIC scores in the bupivacaine than saline groups at 30 minutes and 24 hours posttreatment. No statistically significant between group differences were found in HIT-6 scores or in average acute medication use. Only one serious adverse event was reported and it was not treatment-related.

Another 2015 publication by Cady on this study reported on 1- and 6- month follow-up results and on supplemental secondary end points.<sup>[4]</sup> To control for multiple comparisons, the cutoff for statistical significance for the supplemental secondary end points was  $p < 0.01$ . There were no statistically significant differences between groups for the reported supplementary secondary outcomes. These outcomes include the number of headache days per month, the mean pain score and quality of life measures. A post hoc power analysis revealed that the study was underpowered to detect significant differences in

secondary outcomes. Some results were suggestive of a possible long-term effect (e.g. the bupivacaine group had a lower, albeit nonsignificant number of headache days in the month posttreatment than the placebo group (17 vs 23). However, a study with a larger sample size is needed to confirm whether or not 1- or 6-month results are significantly better after bupivacaine versus placebo treatment.

## SEVERE ACUTE HEADACHE TREATED IN AN EMERGENCY SETTING

The published literature on SPG blocks to treat severe acute headache consists of one double-blind placebo-controlled RCT.<sup>[6]</sup> The study included patients between the ages of 18 and 65 who presented to the emergency department with a frontal-based crescendo-onset headache and a negative neurological examination. The study focused on frontal-based headaches because these were considered most likely to respond to SPG blocks. Headaches were not classified into specific types but patients with sudden-onset headache were excluded. Ninety-three patients met eligibility criteria and were randomized 1:1 to receive treatment with bupivacaine 0.5% (n=45) or a saline placebo (n=48) applied using the Tx360® device. The intervention consisted of one treatment session. The primary outcome was a 50% absolute pain reduction on a 100-mm visual analog scale (VAS) 15 minutes post-treatment. Four patients, two in each group, withdrew before receiving the intervention and two were deemed ineligible after randomization. Thus, 41 patients in the bupivacaine group and 46 in the placebo group were included in the primary analysis.

For the primary outcome, 20 (49%) patients in the bupivacaine group and 19 (41%) patients in the placebo group had at least a 50% reduction in the mean VAS score. The difference between groups was not statistically significant (difference, 7.5%; 95% CI, -13% to 27%). Secondary outcomes including at least a 19mm reduction in VAS, percent of patients who were headache-free 15 minutes postintervention and percent of patients who were nausea-free 15 minutes postintervention, also did not differ significantly between groups. Seventy-six (88%) patients were available for follow-up after 24 hours. The percent of patients headache free at 24 hours was significantly higher in the bupivacaine group (n=26 [72%]) than the placebo group (n=19 [48%]; difference, 25%; 95% CI, 2.6 to 44%). No serious adverse events were reported in either group.

## CLUSTER HEADACHE

No RCTs or non-randomized comparative studies were identified that evaluate intranasal SPG blocks for treating cluster headache. Two small case series in patients with chronic drug-resistant cluster headache (CH) were published by a research group in Milan, Italy<sup>[7,8]</sup> Both studies were small and had methodological limitations limiting the conclusions that can be drawn.

## OTHER PAIN NOT RELATED TO HEADACHE AND MIGRAINE

Al-Qudah (2015) evaluated post-operative pain after endoscopic sinus surgery in a double-blind placebo controlled trial of 60 patients with chronic rhinosinusitis.<sup>[9]</sup> Patients were randomized to receive lidocaine with epinephrine or saline at the end of surgery. Pain was assessed immediately and after 24 hours postoperatively. In addition, the need for rescue analgesia was reported. The immediate pain control was statistically better in the lidocaine with epinephrine group compared to controls. The saline group required more rescue analgesia compared to the lidocaine group. More research is needed to confirm these findings.

Cho (2011) published a prospective double-blind, randomized, placebo-controlled trial which included 60 patients undergoing functional endoscopic sinus surgery (FESS).<sup>[10]</sup> One group was randomly assigned to FESS to receive a block with bupivacaine and epinephrine (n=29) and the control group (n=27) received normal saline. There were no significant improvements in pain after seven days between the two groups.

Ferrante (1998) conducted a double-blind, placebo controlled, crossover study evaluating SPG block for patients with myofascial pain of the head, neck, and shoulders. Patients (n=23) were randomly assigned to one of two groups.<sup>[11]</sup> The first group was assigned to a SPG block with 4% lidocaine, then TPI with 1% lidocaine, and finally SPG block with saline placebo. The second group was assigned to SPG block with saline placebo, then TPI with 1% lidocaine, and lastly SPG block with 4% lidocaine. Each protocol was evaluated for pain at one week intervals. The authors concluded that SPG block with 4% lidocaine was not more effective than placebo and less effective than trigger point injections for the treatment of myofascial pain of the head, neck, and shoulders.

Janzen (1997) published a double-blind, placebo controlled study which evaluated sphenopalatine blocks in patients with fibromyalgia (n=42) and myofascial pain syndrome (n=19).<sup>[12]</sup> Patients were assigned to lidocaine and sterile water or placebo. Pain was measured prior to and after treatment, and 28 days after treatment. There were no reported significant differences between the two groups for any pain outcomes.

## PRACTICE GUIDELINE SUMMARY

No practice guidelines were identified.

## SUMMARY

There is not enough research to show that sphenopalatine ganglion block for any indication improves health outcomes. In addition, no practice guidelines recommend sphenopalatine ganglion block. Therefore, sphenopalatine ganglion block is considered investigational for all indications.

## REFERENCES

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13. BlueCross BlueShield Association Medical Policy Reference Manual "Sphenopalatine Ganglion Block for Headache."

## CODES

**NOTE:** It has been mentioned that this procedure is sometimes reported with CPT code 64505 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.

Codes	Number	Description
CPT	64505	Injection, anesthetic agent; sphenopalatine ganglion
	64999	Unlisted procedure, nervous system
HCPCS		None

*Date of Origin: May 2017*