Intranasal Anesthetic and Blocks for the Treatment of Headaches and Migraines

Policy Number: 2.01.508  Last Review: 3/2016
Origination: 2/2014  Next Review: 2/2017

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for intranasal anesthetic and blocks for the treatment of headaches and migraines. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
The use of intranasal anesthetic or blocks (e.g., sphenopalatine blockade) for the treatment of headaches and migraines is considered investigational.

Description of Procedure or Service
The procedure targets a nerve cluster with in the nasal cavity called the sphenopalatine ganglion by using a specialized FDA cleared nasal applicator to deliver medication directly to the nerve. Two applicators are soaked in the local anesthetic chosen, and one applicator is advanced along the superior border of the middle turbinates of each nostril until the tip comes into contact with the mucosa overlying the sphenopalatine ganglion. Then additional local anesthetic is instilled over each cotton-tipped applicator. The applicator acts as a tampon that allows the local anesthetic to remain in contact with the mucosa overlying the ganglion. The applicators are removed after 20 minutes.

The MiRx Protocol is one example of a treatment program made up of two parts, a medical component and a physical component. A nasal application of a topical anesthetic is administered using an FDA cleared applicator to target the nerve. The purpose of this is to relieve the headache pain. The second part then attempts to treat and rehabilitate the underlying condition. This could include anything from physical therapy to chiropractic adjustments, corrective ergonomic recommendations, cranial therapy, diet modifications, or stress management therapy.
The Tx360® Nasal Applicator is a FDA cleared, sterile, single-use medication delivery device. The applicator is used to deliver small amounts of medication onto the mucosa covering the SPG. In the clinical studies, 0.6 mL of 0.5% bupivacaine was delivered through the Tx360®, and 0.3 mL was injected into each nasal pathway to target the mucosa area associated with the Sphenopalatine Ganglion to perform a SPG blockade. The SPG is a small concentrated structure of neuronal tissue that resides within the pterygopalatine fossa in close proximity to the sphenopalatine foramen and is innervated by the maxillary division of the trigeminal nerve. SPG blockade may be used as an acute treatment (one-time) and for preventative treatment for chronic migraines using repetitive SPG blocks (2 times per week for 6 weeks).

**Rationale**

Migraine is a common headache disorder with a prevalence in the United States of approximately 18% in women and 6% in men. (1) According to the International Headache Society, migraine headache is a recurrent disorder with attacks lasting 4-72 hours. Typical features of migraine headaches include unilateral location, pulsating quality, moderate or severe intensity and associated symptoms such as nausea, photophobia, and/or phonophobia. (2)

A variety of medications are used to treat acute migraine episodes. These include medications that are taken at the outset of an attack to abort the attack (triptans, ergotamines), and medications to treat the pain and other symptoms of migraines once they are established (non-steroidal anti-inflammatory drugs (NSAIDS), narcotic analgesics, antiemetics). Prophylactic medication therapy may be appropriate for individuals 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 A injections are a Food and Drug Administration (FDA)-approved treatment for chronic migraine (migraines occurring on at least 15 days per month for at least 3 months).

A double-blind, randomized, controlled trial tested the hypothesis that intranasal ketamine would affect migraine with prolonged aura. These researchers examined the effect of 25-mg intranasal ketamine on migraine with prolonged aura in 30 migraineurs using 2-mg intranasal midazolam as an active control. Each subject recorded data from 3 episodes of migraine. A total of 18 subjects completed the study. Ketamine reduced the severity (p = 0.032) but not duration of aura in this group, whereas midazolam had no effect. The authors concluded that these data provided translational evidence for the potential importance of glutamatergic mechanisms in migraine aura and offer a pharmacologic parallel between animal experimental work on cortical spreading depression and the clinical problem. Drawbacks of this study included small number of patients and the design of the study did not exclude an effect of midazolam. These findings need to be validate by well-designed studies with more patients, higher doses of ketamine and
subjects with more migraine attacks. The authors stated that their study does not endorse the widespread use of ketamine in migraine aura. (3)

In a double-blind, parallel-arm, placebo-controlled, randomized pilot study, Cady et al (2015) examined if repetitive SPG blocks with 0.5 % bupivacaine delivered through the Tx360 are superior in reducing pain associated with CM compared with saline. Up to 41 subjects could be enrolled at 2 headache specialty clinics in the US. Eligible subjects were between 18 and 80 years of age and had a history of CM defined by the second edition of the International Classification of Headache Disorders appendix definition. They were allowed a stable dose of migraine preventive medications that was maintained throughout the study. Following a 28-day baseline period, subjects were randomized by computer-generated lists of 2:1 to receive 0.5 % bupivacaine or saline, respectively. The primary end-point was to compare numeric rating scale scores at pre-treatment baseline versus 15 minutes, 30 minutes, and 24 hours post-procedure for all 12 treatments. Sphenopalatine ganglion blockade was accomplished with the Tx360, which allows a small flexible soft plastic tube that is advanced below the middle turbinate just past the pterygopalatine fossa into the intranasal space. A 0.3 cc of anesthetic or saline was injected into the mucosa covering the SPG. The procedure was performed similarly in each nostril. The active phase of the study consisted of a series of 12 SPG blocks with 0.3 cc of 0.5 % bupivacaine or saline provided 2 times per week for 6 weeks. Subjects were re-evaluated at 1 and 6 months post-final procedure. The final dataset included 38 subjects, 26 in the bupivacaine group and 12 in the saline group. A repeated measures analysis of variance showed that subjects receiving treatment with bupivacaine experienced a significant reduction in the numeric rating scale scores compared with those receiving saline at baseline (M = 3.78 versus M = 3.18, p = 0.10), 15 minutes (M = 3.51 versus M = 2.53, p < 0.001), 30 minutes (M = 3.45 versus M = 2.41, p < 0.001), and 24 hours after treatment (M = 4.20 versus M = 2.85, p < 0.001), respectively. Headache Impact Test-6 scores were statistically significantly decreased in subjects receiving treatments with bupivacaine from before treatment to the final treatment (Mdiff = -4.52, p = 0.005), whereas no significant change was seen in the saline group (Mdiff = -1.50, p = 0.13). The authors concluded that SPG blockade with bupivacaine delivered repetitively for 6 weeks with the Tx360 device demonstrated promise as an acute treatment of headache in some subjects with CM. Statistically significant headache relief is noted at 15 and 30 minutes and sustained at 24 hours for SPG blockade with bupivacaine vs saline. They stated that the Tx360 device was simple to use and not associated with any significant or lasting adverse events; further research on SPG blockade is warranted.(9)

In a randomized placebo-controlled trial, Schaffer et al (2015) examined the effectiveness of non-invasive SPG block for the treatment of acute anterior headache in the emergency department (ED) using a novel non-invasive delivery device. This study was completed in 2 large academic EDs. Bupivacaine or normal saline solution was delivered intra-nasally (0.3 ml per side) with the Tx360 device. Pain and nausea were measured at 0, 5, and 15 minutes by a 100-mm visual analog scale. The primary end-point was a 50 % reduction in pain at 15 minutes. Telephone follow-up assessed 24-hour pain and nausea through a 0- to
10-point verbal scale and adverse effects. The median reported baseline pain in the bupivacaine group was 80 mm (IQR 66 mm to 93 mm) and 78.5 mm (IQR 64 mm to 91.75 mm) in the normal saline solution group. A 50 % reduction in pain was achieved in 48.8 % of the bupivacaine group (20/41 patients) versus 41.3 % in the normal saline solution group (19/46 patients), for an absolute risk difference of 7.5 % (95 % confidence interval [CI]: -13 % to 27.1 %). As a secondary outcome, at 24 hours, more patients in the bupivacaine group were headache free (24.7 % difference; 95 % CI: 2.6 % to 43.6 %) and more were nausea free (16.9 % difference; 95 % CI: 0.8 % to 32.5 %). The authors concluded that for patients with acute anterior headache, SPG block with the Tx360 device with bupivacaine did not result in a significant increase in the proportion of patients achieving a greater than or equal to 50 % reduction in headache severity at 15 minutes compared with saline solution applied in the same manner.(7)

Summary
The evidence at this time is insufficient to permit conclusions concerning the effect of this treatment on net health outcome. It is considered investigational.

References:

Billing Coding/Physician Documentation Information
64505 Injection, anesthetic agent; sphenopalatine ganglion
64999 Unlisted procedure, nervous system

Additional Policy Key Words
MiRx™ Protocol
Policy Implementation/Update Information

2/1/14  New policy; considered investigational.
2/1/15  Policy revised to include information regarding sphenopalatine ganglion blockades. Remains investigational.
2/1/16  No policy statement changes.
3/1/16  No policy statement changes. Updated rationale and description.

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