Clinical Policy Title: Sphenopalatine ganglion block injections for headache

Clinical Policy Number: 09.02.05

Effective Date: October 1, 2016
Initial Review Date: July 20, 2016
Most Recent Review Date: July 3, 2018
Next Review Date: July 2019

Related policies:

CP# 09.02.02 Invasive treatment for cervicogenic headache and occipital neuralgia
CP# 00.02.02 Botulinum toxin products

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of sphenopalatine ganglion block injections for headache to be investigational/experimental and, therefore, not medically necessary.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

Sphenopalatine ganglion block injections for conditions other than chronic headache are also considered investigational/experimental, and therefore, not medically necessary.

Alternative covered services:

Policy contains:

- Bupivacaine.
- Cluster headache.
- Migraine headache.
- Functional endoscopic sinus surgery.
- Sphenopalatine ganglion block.
• Sphenopalatine ganglion block neurostimulation
• Sphenopalatine ganglion block radiofrequency ablation

Background

The sphenopalatine ganglion is an autonomic mass of nerve cell bodies found in the pterygopalatine fossa (trench) in the skull, just behind the nose. The nerve cells are linked to the trigeminal nerve, the main nerve involved in headache, and thus the sphenopalatine ganglion has been the target of numerous treatments to block the source(s) of pain in patients with chronic headaches.

Sphenopalatine ganglion blocks have been used to treat (among other disorders)
• Cluster headaches.
• Migraine headaches.
• Post-dural puncture headaches.
• Trigeminal neuralgia.
• Herpes zoster.
• Paroxysmal hemicrania.
• Cancer of the head and neck.
• Atypical facial pain.
• Complex regional pain syndrome.
• Temperomandibular disorder.
• Nasal contact point headache.
• Vasomotor rhinitis.

Since the early 1900s, the sphenopalatine ganglion has been targeted to relieve head pain; among the earliest of these treatments involved applying numbing medications on cotton swabs to the back of the nose. Another technique later used was injecting patients through an area on the cheek, using alcohol. Relatively recently, the U.S. Food and Drug Administration has approved catheters (thin plastic tube placed in the nose) to facilitate insertion of numbing medication injected in and around the sphenopalatine ganglion. Three catheters approved are Sphenocath® Allevio® and Tx 360®. Anesthetics used in sphenopalatine ganglion injections to control head pain include bupivacaine and lidocaine (Nair, 2017).

Other methods used in sphenopalatine ganglion block for head pain in the disorders listed above include (but are not limited to) hypothalamic deep brain stimulation, laser therapy, neurostimulation, occipital nerve stimulation, oral calcitonin gene-related peptide antagonist telcagepant, oxygen inhalation, patent foramen ovale closure, radiofrequency ablation, surgical decompression of occipital nerves, triptans, vagus nerve stimulation, and zygomaticotemporal neurectomy. Many of the above are device-based treatments in preliminary stages of clinical trials.

Injections to relieve pain for the conditions listed above to block head pain in the sphenopalatine ganglion begins with the insertion of a catheter into one nostril, and requires the use of an X-ray machine to ensure
the injection is placed correctly. The sphenopalatine ganglion anesthetic medication is then injected through an area on the cheek, and the process is repeated in the other nostril. These procedures are conducted in physician offices, and take just minutes to accomplish. Blood pressure and heart rate are checked both before and after the procedure (Charleston, 2016).

Sphenopalatine ganglion neuromodulation for treating cluster headaches is still not frequently performed; as of 2017, about 300 such procedures have been performed in European nations (Tepper, 2017). Functional endoscopic sinus surgery, while not a type of headache, is another condition for which sphenopalatine ganglion block has been more commonly used in recent years.

Sphenopalatine ganglion block injections can be performed once, or as often as needed to reduce pain. The injections can also be used in pediatric patients, for similar conditions used in adults, such as migraine headaches (Dance, 2017).

A position statement from the European Headache Foundation recommends sphenopalatine palatine block stimulation before deep brain stimulation in chronic cluster headaches (Martilletti, 2013), as did the American Headache Society which gave a Level B recommendation for acute treatment (for cluster headache) using sphenopalatine ganglion block stimulation (Robbins, 2016). However, neither of these, nor other guidelines, addresses sphenopalatine ganglion block injections for headache.

**Searches**

Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on May 17, 2018. Search terms were: “sphenopalatine ganglion injection,” and “sphenopalatine ganglion block injection.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**
One early study that tested anesthesia applied to the sphenopalatine ganglion that later would be injected was a non-controlled study in which 12 of 23 patients who suffered chronically from migraine headaches achieved complete relief, eight of whom did so within five minutes of administration, after intranasal instillation of 0.4 mL of a four percent lidocaine solution. In addition, nausea was aborted in in five of six responders who had nausea (Kudrow, 1995).

A study of 20 patients suffering from chronic cluster headaches who were drug resistant included an injection of a mixture of local anesthetics and corticosteroids. Symptoms improved significantly, but only temporarily, in 11 of the 20 patients. This was an early report illustrating the ability of SPG injections to reduce pain before more invasive surgical techniques are attempted (Felisati, 2006).

Probably the most common way to evaluate sphenopalatine ganglion block injections is placebo-controlled studies that compare headache patients injected with bupivacaine vs. those injected with saline through the catheter. One review of 52 patients who were given injections 10 minutes before functional endoscopic sinus surgery showed that seven days after surgery, the mean visual analog pain scale score for the medicine group (given two mL of 0.25 percent bupivacaine) was lower than the saline group; but the difference was of borderline statistical significance (0.48 vs. 1.12, p=0.053). There were no differences in other functional outcome measures between the two groups (Cho, 2011).

A placebo-controlled study compared outcomes for chronic migraine sufferers given injections of 0.3 cc of 0.5 percent bupivacaine (n=26) or saline (n=12) through the Tx360® tube, twice a week for six weeks. Significantly greater reductions in pain were observed in the medicine group 15 minutes, 30 minutes, and 24 hours after the procedure throughout the trial (Cady R, 2015). A follow up to this report documented a greater decrease in post-operative headache days in the bupivacaine group (Cady RK, 2015). Another study of patients with acute anterior headache receiving sphenopalatine ganglion block with the Tx360® tube comparing bupivacaine and saline showed no significant increase in the proportion of patients achieving a greater than or equal to 50 percent reduction in headache severity at 15 minutes compared with only saline solution applied in the same manner (Schaffer, 2015).

A group of 42 patients who underwent sphenopalatine ganglion block injections (of one mL of absolute alcohol) were sub-divided into three categories; 1) cluster headache; 2) persistent idiopathic facial pain; and 3) other. The rate of at least 50 percent pain relief for at least one month was 67.2 percent, with mean pain relief of 10.3 months. The “other” group rate of 40 percent was much lower than the other two (76.5 and 85.7 percent). Recurrence rates were similar for each group (Kastler, 2014).

A review of sphenopalatine ganglion block for refractory chronic cluster headaches had positive results for pain relief, attack frequency, medication use, and quality of life, with elevated adverse events in the first 30 days after intervention. The authors state that long-term follow-up data is needed (Sanchez-Gomez, 2018). A systematic review of 19 studies of sphenopalatine ganglion block concluded the strongest evidence was for cluster headaches, with some evidence for successfully treating trigeminal neuralgia, migraines, reducing the needs of analgesics after endoscopic sinus surgery and packing removal after nasal operations. Again, the study asserts replication of these findings are needed (Ho, 2017).
In addition to headache, sphenopalatine ganglion block injections of anesthesia are used in endoscopic sinus surgery. One review found that surgical patients administered sphenopalatine ganglion block in addition to general anesthesia were discharged sooner, required less fentanyl during recovery, and had higher patient satisfaction scores, with no difference in incidence of nausea and vomiting (DeMaria, 2012). One review could identify only two studies that qualified for a meta-analysis. While the nerve block group had a significantly lower (p<.009) amount of bleeding than controls, authors caution that more extensive research be performed before drawing any conclusions (Shamil, 2018).

Another study involving bupivacaine divided 45 functional endoscopic sinus surgery patients into three equal groups, namely those injected with saline, bupivacaine (0.5 percent), and levobupivacaine (0.5 percent) immediately after general anesthesia. Pain scores 2, 4, and 24 hours after surgery were significantly lower for the two medicine groups, which also required fewer additional analgesics in the first 24 hours post-operative. The medicine groups had higher patient and surgeon satisfaction scores, but there were no significant differences between groups in post-surgical complications (Kesimci, 2012). Other studies involving bupivacaine as an sphenopalatine ganglion block continue, but involve applications of the drug that are applied, not injected (Shaffer, 2015).

Two recent journal articles on sphenopalatine ganglion block injections both showed positive results for patients injected with an anesthetic. One study administered 25 or 50 IU of onobotulinumtoxinA in 10 patients with intractable chronic cluster headache, and found a significantly reduced number of cluster headache attacks (18 to 11 per week), but with 11 adverse events within four weeks (Bratbak, 2016). Another involved injections of either 2 mL of saline or two percent lidocaine with epinephrine to 60 persons with chronic rhinosinusitus undergoing endoscopic sinus surgery; post-operative pain severity was significantly lower for the lidocaine group, and only five required rescue anesthesia, versus 12 in the saline group (Al-Qudah, 2016).

A recent study of patients with trigeminal neuralgia compared 50 patients given medical therapy with 26 patients given injections of 2 mg. bupivacaine and 1 mg. prilocain (anesthetic) and 1 ml fentanyl, 0.5 ml betametasone disodium phosphate plus 0.5 ml opaque. The injection group had a significant improvement in visual analog scale score after three days and one month, but not after six months; the medical group had significant improvements only after six months (Coven, 2016).

A recent (uncontrolled) study of 10 patients given bilateral injections of 25 IU of onabotulinumtoxinA (typically given in a lower dose than lidocaine) in a single session to treat chronic migraine headache found that after 12 weeks, the number of moderate and severe headache days was reduced by over 50 percent for eight of the subjects, indicating that placebo-controlled studies of this treatment are merited (Bratbak, 2017).

Little research has been done on sphenopalatine ganglion block for children. One prospective, double-blind, randomized controlled trial of 100 children undergoing palatoplasty compared those given general anesthesia with and without sphenopalatine ganglion block (study and control groups). The study group had significantly lower postsurgical pain-free duration (19.46 versus 87.59 minutes) and lower mean blood
loss (62 versus 105.5 mL), plus superior surgical field and postoperative reduction (Parameswaran, 2018).

In general, while sphenopalatine ganglion block injections have shown some promise in reducing pain for chronic headache sufferers and patients with other conditions, the evidence is limited and more studies are needed to better assess the efficacy of this technology.

Policy updates:

A total of two guidelines/other and six peer-reviewed references were added to, and six peer-reviewed references removed from, this policy in May, 2018.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al-Qudah (2016)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Pain reduction in persons with chronic rhinosinusitis undergoing surgery</td>
<td>• 60 subjects, given 2 mL of 2% lidocaine with epinephrine vs. 2 mL saline after surgery.</td>
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<tr>
<td></td>
<td>• Pain reduction greater in lidocaine group immediately after surgery, and 6/24 hours after.</td>
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<td>• 12 patients in lidocaine group required rescue anesthesia, vs. 5 in saline group.</td>
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<td></td>
<td>• Conclusion: SBG injection safe, simple, noninvasive, effective in short term pain control.</td>
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<tr>
<td>Bratbak (2016)</td>
<td>Key points:</td>
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<tr>
<td>Reduction in number of attacks in subjects with intractable chronic cluster headache.</td>
<td>• 10 subjects, given 25 or 50 IU injections of onabotulinumtoxinA, followed 24 weeks.</td>
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<td></td>
<td>• Average attacks reduced from 18 prior to treatment to 11 in weeks 3 and 4; reductions documented in 5 of 6 months after therapy.</td>
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<tr>
<td>Cady R (2015)</td>
<td>Key points:</td>
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<tr>
<td>Pain reduction in persons with chronic migraine headaches, via injections through Tx360 catheter.</td>
<td>• 26 persons injected with 0.3 cc of bupivacaine (0.5%), 12 with saline.</td>
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<td>• Injections twice a week for six weeks, re-evaluated 1/6 months after final procedure.</td>
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<td>• Significantly greater reduction in pain for medicine group at 10 mins, 30 mins, 24 hours.</td>
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<td></td>
<td>• No lasting adverse events for bupivacaine group.</td>
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<tr>
<td>Kesimci (2012)</td>
<td>Key points:</td>
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<tr>
<td>Reduction in pain and post-operative complications in patients undergoing functional endoscopic sinus surgery (FESS)</td>
<td>• 45 subjects divided into three groups of 15 each.</td>
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<td>• Patients given saline, bupivacaine 0.5%, or levobupivacaine 0.5% after general anesthesia.</td>
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<td>• Pain scores checked on arrival to postanesthesia care unit, and 2/6/24 hours later.</td>
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<td>• Two medicine groups showed significant reductions in visual analog scale pain scores.</td>
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<td>• Fewer in two medicine groups required additional analgesics.</td>
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<td></td>
<td>• Two medicine groups had higher patient and surgeon satisfaction.</td>
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<td></td>
<td>• No difference in groups in post-operative complications.</td>
</tr>
<tr>
<td>Cho (2011)</td>
<td>Key points:</td>
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<tr>
<td>Reduction in post-operative pain after FESS</td>
<td>• 52 subjects undergoing bilateral FESS.</td>
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<td></td>
<td>• Patients given 2 mL injections of 0.25% bupivacaine or saline, 10 minutes before surgery.</td>
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<td>• Pain scale measured for both groups 0/730 days post-operative.</td>
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<td>• Day 7 pain scale lower for bupivacaine group (0.48 vs. 1.12, p=0.053).</td>
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<tr>
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<td>• No other differences in other outcome measures between two groups.</td>
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</tbody>
</table>
References

Professional society guidelines/other:


Peer-reviewed references:


Schaffer JT, Hunter BR, Ball KM, Weaver CS. Noninvasive sphenopalatine ganglion block for acute headache


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>CPT Code</th>
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<td>64505</td>
<td>Injection, anesthetic agent; sphenopalatine ganglion</td>
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<tr>
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<tr>
<td>G43.001-G43.919</td>
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