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: August 17, 2016
Next Review Date: August 2017

Policy contains:
- Sphenopalatine ganglion block
- Cluster headache
- Migraine headache
- Bupivacaine
- Functional endoscopic sinus surgery

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 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 can be accessed at http://ahca.myflorida.com/Medicaid/.

Sphenopalatine ganglion block injections for conditions other than chronic headache are also considered investigational, and therefore, not medically necessary.
Alternative covered services:

None.

Background

The Sphenopalatine ganglion (SPG) 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.

SPG 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 SPG 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 FDA has approved catheters (thin plastic tube placed in the nose) to facilitate insertion of numbing medication injected in and around the SPG. Three catheters approved are Sphenocath®, Allevio® and Tx 360®. Anesthetics used in SPG injections to control head pain include bupivacaine and lidocaine.

Other methods used in SPG 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 calcitonine 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 SPG 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 SPG 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.

Functional endoscopic sinus surgery (FESS), while not a type of headache, is another condition for which SPG block has been more commonly used in recent years.

SPG block injections can be performed once, or as often as needed to reduce pain.

**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 June 14, 2016. Search terms were: “sphenopalatine ganglion block” 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 of injecting anesthesia through catheters used in vitro models of the spinal canal. The (then) new Spinocath catheter, CoSpan catheter, and 29-gauge Quincke needle were used to inject bupivacaine and lidocaine, and levels of these anesthetics were subsequently measured. Both reached a peak quickly and did not decrease over 10 minutes of measurement (Holst, 1998).
One study that tested anesthesia applied to the SPG 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 4% lidocaine solution. In addition, nausea was aborted in in 5 of 6 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, as each patient was drug resistant. 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 SPG 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 (FESS) showed that seven days after surgery, the mean visual analog pain scale score for the medicine group (given 2 mL of 0.25% bupivacaine) was lower than the saline group, but the difference was not statistically significant (0.48 vs. 1.12, p=0.053). There were no differences in other functional outcome measures between the two groups (Cho, 2011).

Another placebo-controlled study compared outcomes for chronic migraine sufferers given injections of 0.3 cc of 0.5% bupivacaine (n=26) or saline (n=12) through the Tx360® tube, provided 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 RL, 2015).

In addition to headache, sphenopalatine ganglion block injections of anesthesia are used in endoscopic sinus surgery. One review found that surgical patients administered SPG 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).

Another study involving bupivacaine divided 45 FESS patients into three equal groups, namely those injected with saline, bupivacaine (0.5%), and levobupivacaine (0.5%) 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 SPG block continue, but involve applications of the drug that are applied, not injected (Shaffer, 2015).
The two latest (spring 2016) journal articles on SPG 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 2% lidocaine with epinephrine to 60 persons with chronic rhinosinusitis undergoing endoscopic sinus surgery; post-operative pain severity was significantly lower for the lidocaine group, and only five (5) required rescue anesthesia, vs. 12 in the saline group (Al-Qudah, 2016).

In general, while SGB 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:**

None.

**Summary of clinical evidence:**

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<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Al-Qudah (2016)</td>
<td>Key points:</td>
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| Pain reduction in persons with chronic rhinosinusitis undergoing surgery | - 60 subjects, given 2 mL of 2% lidocaine with epinephrine vs. 2 mL saline after surgery  
- Pain reduction greater in lidocaine group immediately after surgery, and 6/24 hours after  
- 12 patients in lidocaine group required rescue anesthesia, vs. 5 in saline group  
- Conclusion: SBG injection safe, simple, noninvasive, effective in short term pain control |
| Bratbak (2016)  | Key points:                       |
| Reduction in number of attacks in subjects with intractable chronic cluster headache | - 10 subjects, given 25 or 50 IU injections of onobotulinumtoxinA, followed 24 weeks  
- Average attacks reduced from 18 prior to treatment to 11 in weeks 3 and 4; reductions documented in 5 of 6 months after therapy |
| Cady R (2015)   | Key points:                       |
| Pain reduction in persons with chronic migraine headaches, via injections through Tx360 catheter | - 26 persons injected with 0.3 cc of bupivacaine (0.5%), 12 with saline  
- Injections twice a week for six weeks, re-evaluated 1/6 months after final procedure  
- Significantly greater reduction in pain for medicine group at 10 mins, 30 mins, 24 hours  
- No lasting adverse events for bupivacaine group |
| Kesimci (2012)  | Key points:                       |
| Reduction in pain and post-operative complications in patients undergoing functional endoscopic sinus | - 45 subjects divided into three groups of 15 each  
- Patients given saline, bupivacaine 0.5%, or levobupivacaine 0.5% after general anesthesia  
- Pain scores checked on arrival to postanesthesia care unit, and 2/6/24 hours later |
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| surgery (FESS) | - Two medicine groups showed significant reductions in visual analog scale pain scores  
                   - Fewer in two medicine groups required additional analgesics  
                   - Two medicine groups had higher patient and surgeon satisfaction  
                   - No difference in groups in post-operative complications |
| Cho (2011) | **Key points:**  
                   - 52 subjects undergoing bilateral FESS  
                   - Patients given 2 mL injections of 0.25% bupivacaine or saline, 10 minutes before surgery  
                   - Pain scale measured for both groups 0/7/30 days post-operative  
                   - Day 7 pain scale lower for bupivacaine group (0.48 vs. 1.12, p=0.053)  
                   - No other differences in other outcome measures between two groups |
| Felsati (2006) | **Key points:**  
                   - 20 subjects given injections (mixture of local anesthetics and corticosteroids)  
                   - Symptoms improved significantly, but temporarily in 11 of 20 subjects  
                   - SBG injections showed potential to alleviate symptoms in headache patients |

**Glossary**

**Sphenopalatine ganglion block (SPG)** — Treatment with anesthetics to block pain through the sphenopalatine ganglion, an autonomic knotlike mass of nerve cell bodies found in the pterygopalatine fossa (trench) in the skull, just behind the nose.

**Cluster headache** — Headache characterized by intense pain in or around one eye and one side of the head, which occur in cyclical patterns of clusters.

**Migraine headache** — Type of headache (affecting 28 million Americans) characterized by pounding head, nausea, vomiting, and light sensitivity.

**Bupivacaine** — An anesthetic often used in injections into the sphenopalatine ganglion to reduce pain from chronic headaches.

**Functional endoscopic sinus surgery (FESS)** — A surgical treatment of sinusitis and nasal polyps, based primarily on establishing drainage pathways.

**References**

**Professional society guidelines/other:**


Peer-reviewed references:


**Clinical trials:**

Searched clinicaltrials.gov on June 17, 2016 using term “sphenopalatine ganglion block.” Open Studies. 11 studies found, four (4) relevant.

University of Arkansas. Sphenopalatine Ganglion Block for Postdural Puncture Headache in the Emergency Department. ClinicalTrials.gov website.


**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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