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, 2017
Next Review Date: August 2018

Related policies:

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

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’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 Select Health of South Carolina 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. Select Health of South Carolina’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. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of sphenopalatine ganglion block injections for headache to be investigational and, therefore, not medically necessary.

Limitations:

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

Alternative covered services:

- Sphenopalatine ganglion block neurostimulation
- Sphenopalatine ganglion block radiofrequency ablation

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.
- Temporomandibular 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 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 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**
Select Health of South Carolina 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 21, 2017. 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**

A position statement from the European Headache Foundation recommends SGB 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 using SGB stimulation (Robbins, 2016). However, neither of these, nor other guidelines, addresses SPG block injections for headache.

One early 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 percent lidocaine solution. In addition, nausea was aborted 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 percent 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 percent 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 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 SPG block continue, but involve applications of the drug that are applied, not injected (Shaffer, 2015).

Two recent 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 percent 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 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).
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:**

A total of two guidelines/other and three peer reviewed references were added to this policy in 2017.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</thead>
<tbody>
<tr>
<td>Al-Qudah (2016)</td>
<td><strong>Key points:</strong></td>
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| Pain reduction in persons with chronic rhinosinusitus 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 onabotulinumtoxinA, 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 surgery (FESS) | • 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.  
• 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:**                   |
| Reduction in post-operative pain after FESS | • 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. |
<p>| Felsati (2006)    | <strong>Key points:</strong>                   |
| Reduction in symptoms for | • 20 subjects given injections (mixture of local anesthetics and corticosteroids). |</p>
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Subjects with chronic cluster headaches | • Symptoms improved significantly, but temporarily in 11 of 20 subjects.  
• SBG injections showed potential to alleviate symptoms in headache patients. |

References

Professional society guidelines/other:


Peer-reviewed references:


**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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