

# Injection Therapy for Headache Management



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**Medical Policy #: 02.01.52**

**Original Effective Date:** December 2013

**Reviewed:** July 2022

**Revised:** July 2022

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

## DESCRIPTION

Acute/chronic migraine and acute/chronic non-migraine headaches are common conditions and available treatments are not always effective. A proposed treatment options include blocking the sphenopalatine ganglion (SPG) nerve by applying an intranasal topical anesthetic or peripheral nerve injections/nerve blocks may also be used at various locations around the face and neck (occipital nerve, trigeminal nerve, supraorbital nerve, and stellate ganglion) to reduce pain and inflammation using injectable anesthetic, steroids, or other agents to manage headaches.

As many as 90% of all primary headaches fall under a few categories including migraine, tension-type, and cluster headache. While episodic tension-type headache (TTH) is the most frequent headache type in population-based studies, migraine is the most common diagnosis in individuals. Cluster headache typically leads to significant disability and most of these individuals will seek medical attention.

## Chronic Daily Headaches

Chronic daily headache (CDH) is a descriptive term that encompasses several different specific headache diagnoses characterized by frequent headaches. Primary CDH subtypes of long duration (i.e., four hours or more) include chronic migraine and chronic tension-type headache. Primary headache types of shorter duration that can be chronic and occur daily are chronic cluster headache, chronic paroxysmal hemicrania and primary headache disorders such as cervicogenic headache.

- **Chronic Migraine:** Migraine is a common disabling primary headache disorder. Chronic migraine headache is defined as greater than or equal to 15 days per month lasting 4 hours a day or longer in an adult individual for more than 3 months, with features of migraine on at least 8 days per month.
- **Chronic tension type headache:** Frequent episodic tension type headache, with daily or very frequent episodes of headache, typically bilateral, pressing to tightening in quality and of mild to moderate intensity, lasting hours, to days or unremitting. The pain does not worsen with routine physical activity, but may be associated with mild nausea, photophobia or phonophobia.
- **Chronic cluster headache:** Chronic cluster headaches is one of the trigeminal autonomic cephalalgias (TACs), a group of primary headache disorders characterized by unilateral trigeminal distribution pain that occurs in association with ipsilateral cranial autonomic features. Cluster headache is characterized by attacks of severe unilateral, orbital, supraorbital or temporal pain. In the episodic form, attacks occur daily, usually one to eight times a day for several weeks, followed by a period of remission. The chronic form of cluster headaches occurs for more than 1 year without remissions, or with remission periods lasting less than 1 month.
- **Cervicogenic headache:** The clinical features of cervicogenic headache may mimic those associated with primary headache disorders (e.g., tension-type headache, migraine, or hemicranias continua), making it difficult to distinguish among headache types. Cervicogenic headaches is characterized by continuous, unilateral head pain radiating from the occipital areas to the front area, with associated neck pain and ipsilateral shoulder or arm pain. The headache is moderate in intensity with non-throbbing character. It is described as dull, boring, dragging pain that can fluctuate in intensity. The duration of the headache may range from a few hours to several days, and in some cases several weeks. The pain can be exacerbated by neck movements and is usually caused by neck trauma.
  - The anatomic point for cervicogenic headache is the trigeminocervical nucleus in the upper cervical spinal cord, where sensory nerve fibers in the descending tract of the trigeminal nerve are believed to interact with sensory fibers from the upper cervical roots. This functional intersection of upper cervical and trigeminal sensory pathways is thought to allow bidirectional transmission of pain signals between the neck and the trigeminal sensory receptor fields of the face and head.

- Cervicogenic headache is typically caused by a disorder of the cervical spine and its component bony, disc and/or soft tissue elements, usually but not invariably accompanied by neck pain.

Post dural puncture headache (PDPH) is a common complication of lumbar puncture. This headache occurs with low cerebrospinal fluid volume from a leak at the site of the dural puncture, resulting in low cerebrospinal pressure and intracranial hypotension. Patients undergoing epidural anesthesia are also at risk for PDPH due to unintended dural puncture, which has been reported to occur in <1% to 6% of obstetric patients. PDPH is characterized by a bilateral frontal or occipital headache that worsens with sitting or standing and is relieved in the supine position. Associated symptoms may include nausea, neck stiffness, low back pain, tinnitus, and visual disturbances. The reported incidence of PDPH as a complication of lumbar puncture is variable, ranging from 10% to 40% of lumbar puncture procedures. Incidence may be as low as 2% when small gauge, non-cutting needles are used.

A variety of medications are used to treat acute/chronic migraine episodes. These include medications taken at the onset of an attack to abort the attack (triptans, ergotamine's) and medications to treat the pain and other symptoms of migraines once they are established (nonsteroidal anti-inflammatory drugs, antiemetics). Prophylactic medication therapy may be appropriate for people with migraines that occur more than 2 days per week. In addition to medication, behavioral treatments (e.g., relaxation, cognitive therapy) are used to manage migraine headache. Botulinum toxin type A injections are FDA-approved treatment for chronic migraine prophylaxis (*see Pharmacy Policy 05.01.02 Neuromuscular Blocking Agents*).

Severe acute/chronic cluster headaches may be treated with abortive therapy including breathing 100% oxygen, and triptan medications. Other medications used to treat cluster headaches include steroids, calcium channel blockers, and nerve pain medications. Due to the severity of pain associated with cluster headaches, patients may seek emergency treatment. Tension-type headaches are generally treated with over-the-counter pain medication.

## **Sphenopalatine Ganglion (SPG) Block(s) and Application of Injections/Nerve Blocks to the Occipital Nerve, Trigeminal Nerve, Supraorbital Nerve and Stellate Ganglion for Headache Management**

### **Clinical Context and Therapy Purpose**

#### **Sphenopalatine Ganglion (SPG) Block(s)**

The purpose of sphenopalatine ganglion (SPG) block(s) in individuals who have chronic headaches (chronic migraine, chronic tension type headache, chronic cluster headache and cervicogenic headache (primary headache disorder) is to provide a treatment option that is an alternative to or an improvement to existing therapies.

The SPG is a group of nerve cells located behind the bony structures of the nose. The nerve bundle is linked to the trigeminal nerve which are associated with the sensory nerves associated with pain perception. SPG 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 proposed procedure for SPG block is to insert an intranasal catheter that is attached to a syringe carrying local anesthetic (e.g., lidocaine, bupivacaine). Once the catheter is in place, the local anesthetic is applied to the posterior wall of the nasal cavity, reaching the SPG. Three catheter devices are commercially available for performing SPG blocks: SpenoCath, Allevio SPG Nerve Block Catheter and Tx360 Nasal Applicator device. The company marketing Tx360 Nasal Applicator device proposes its use in the context of the MiRX protocol. This is a two- part protocol which 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 any number of treatment approaches such as physical therapy, ergonomic modifications, message, and dietary recommendations.

The optimal number and frequency of SPG blocks is unclear. Randomized controlled trials have described a course of treatment for migraines consisting of SPG blocks twice a week for 6 weeks, for a total of 12 treatments.

### **Application of Injections or Nerve Blocks to the Occipital Nerve, Trigeminal Nerve, Supraorbital Nerve and Stellate Ganglion**

Peripheral nerve injections/nerve blocks may also be used at various locations around the face and neck (occipital nerve, trigeminal nerve, supraorbital nerve, and stellate ganglion) to reduce pain and inflammation using injectable anesthetic, steroids, or other agents to manage headaches

Although clinicians commonly utilize these peripheral nerve injections/nerve blocks to manage headaches the procedure has yet to be standardized for this indication.

### **Populations**

The relevant population of interest is individuals with acute/chronic headaches (chronic migraine, chronic tension type headache, chronic cluster headache and cervicogenic headache [primary headache disorder]).

### **Interventions**

The therapy being considered is sphenopalatine ganglion (SPG) block(s) and peripheral nerve injections/ nerve blocks.

SPG block(s) are proposed for both short and long- term treatment of chronic headaches and chronic migraines. When used in the emergency department setting in individuals

with severe acute headaches with mixed etiologies, the goal of treatment is to abort the current headache while the individual is in the emergency department setting.

Peripheral nerve injections/nerve blocks may also be used at various locations around the face and neck (occipital nerve, trigeminal nerve, supraorbital nerve, and stellate ganglion) to reduce pain and inflammation using injectable anesthetic, steroids, or other agents to manage headaches.

### **Comparators**

The following therapies and practices are currently being used to treat chronic headaches (chronic migraine, chronic tension type headache, chronic cluster headache and cervicogenic headache (primary headache disorder): medications, self-management [exercise, relaxation/message], physical therapy, ergonomic modifications, and dietary recommendations).

### **Outcomes**

The general outcomes of interest are reductions in headache frequency, intensity, and medication use. Treatment-related adverse events are minor. A series of injections may be given over several weeks, with follow-up over months to monitor for treatment effect and durability.

### **Review of Evidence**

The published peer reviewed medical literature on sphenopalatine ganglion (SPG) block(s) and peripheral nerve injections/ nerve blocks to treat severe acute headaches/chronic headaches (chronic migraine, chronic tension type headache, chronic cluster headache and cervicogenic headache [primary headache disorder]) consists of randomized controlled trials, systematic reviews, and case series. Studies had small sample sizes and lacked a sham treatment or alternative therapy.

In 2022, the American Academy of Pain Medicine conducted a systematic review to develop practice recommendations for use of percutaneous interventional strategies for the preventive treatment of migraine. Sphenopalatine ganglion blocks received a weak recommendation for chronic migraine prevention based on a very low certainty of evidence. The only therapy evaluated in the guideline that received a strong recommendation for chronic migraine prevention was onabotulinumtoxinA.

UpToDate May 2022: Regarding acute treatment of migraine in adults states the evidence of efficacy for peripheral nerve blocks targeting the occipital nerve, sphenopalatine ganglion (SPG), and trigeminal nerve is limited mainly to small, low-quality trials. Anatomic research has shown that SPG is not as close to the nasal mucosa as previously believed, raising doubt that SPG blockade can be accomplished through intranasal application of local anesthetic.

## **Summary of Evidence**

Based on review of the peer reviewed medical literature regarding the use of sphenopalatine ganglion (SPG) block(s) for the treatment of migraine and non-migraine headaches to include severe acute headache of mixed etiologies the evidence includes randomized controlled trials (RCTs), systematic review and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence is limited to mainly small, low-quality trails. Uncertainty remains regarding the optimal formulation or anesthetic based injections, the long-term efficacy and safety of this procedure versus conservative therapies. Further randomized controlled trials re need to address these questions. The evidence is insufficient to support a conclusion concerning the net health outcomes or benefits associated with this procedure.

Sphenopalatine (SPG) blocks are also being proposed as preventative therapy for chronic migraine and evidence demonstrating reduced migraine frequency, severity or other objective outcomes from robust trails are still needed. For non-migraine headaches to include severe acute headache of mixed etiologies additional studies preferably randomized controlled trials (RCTs) are needed to evaluate SPG blocks for this indication. The evidence is insufficient to support a conclusion concerning the net health outcomes or benefits associated with this procedure.

Based on review of the peer reviewed medical literature regarding peripheral nerve injections/nerve blocks used at various locations around the face and neck (occipital nerve, trigeminal nerve, supraorbital nerve, and stellate ganglion) to reduce pain and inflammation using injectable anesthetic, steroids, or other agents to manage headaches (migraine or non-migraine headaches [to include severe acute headache of mixed etiologies]) is limited. There is considerable variability among clinicians as to injection site(s) and medication selection, indicating a substantial gap in the literature to guide practice and supports the need for further research (controlled clinical trials) in this area. The evidence is insufficient to support a conclusion concerning the net health outcomes or benefits associated with this procedure.

## **Post Dural Puncture Headache**

### **Clinical Context and Therapy Purpose**

The purpose of sphenopalatine ganglion (SPG) block(s) in individuals who have a post dural puncture headache (PDPH) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

### **Populations**

The relevant population of interest is individuals with post dural puncture headache (PDPH).

### **Interventions**

The therapy being considered is sphenopalatine ganglion (SPG) block(s).

## **Comparators**

The following therapies are currently being used to treat post dural puncture headache (PDPH): conservative therapy (e.g., bed rest, oral or intravenous hydration), medication (e.g., analgesics, caffeine, antiemetics), and epidural blood patch. Epidural blood patch is considered the definitive treatment for PDPH.

## **Outcomes**

The general outcomes of interest are reduction in headache intensity and duration, medication use, and avoidance of epidural blood patch use.

## **Review of Evidence**

### **Randomized Controlled Trials**

In 2020, Jespersen et. al., conducted a double-blind RCT comparing administration of SPG block with local anesthetic (lidocaine 4% and ropivacaine 0.5%) to placebo (saline).<sup>17</sup> Twenty patients were randomized to each group with an upright median VAS pain score of 74 and 84 mm, respectively. Eligibility criteria included adult patients  $\geq 18$  years of age with post dural puncture headache (PDPH) defined as moderate-to-severe VAS pain score ( $>30$  mm) in an upright position that develops within 3 days after an intended or accidental dural puncture. The headache must have persisted for at least 1 day after dural puncture and must be intractable to treatment with fluids, caffeine, and acetaminophen, fulfilling eligibility criteria to receive an epidural blood patch. The primary outcome, median pain intensity in the upright position at 30 minutes after SPG block, was 26 mm in the anesthetic group and 37 mm in the placebo group (estimated median difference, 5 mm; 95% CI, -14 to 21;  $p=.53$ ). Patients were offered a rescue SPG block, with open-label anesthetic, if persistent pain was experienced, defined as VAS  $\geq 30$  mm, between 1 hour and 7 days after the initial block. Rescue blocks were required in 65% of patients in each group and were received an average of 1.4 or 1.5 hours following the initial block in the anesthetic and placebo groups, respectively. An epidural blood patch was offered if the rescue block failed to relieve pain. In the anesthetic group, 50% of patients required an epidural blood patch compared with 45% treated with placebo ( $p=.76$ ). Interpretation of epidural blood patch use is limited by broad administration of rescue blocks in both groups. The median time to epidural blood patch was 11 versus 5.5 hour in anesthetic and placebo groups, respectively.

UpToDate July 2021: Regarding post dural puncture headache (PDPH) alternative treatments include bilateral transnasal sphenopalatine block and greater occipital nerve block, the data is limited, and prospective randomized trials are needed to fully evaluate the efficacy of these interventions.

### **Summary of Evidence**

For individuals who have post dural puncture headache (PDPH) who receive sphenopalatine ganglion (SPG) block(s), the evidence includes a randomized controlled trial (RCT). The small randomized, double-blind, placebo-controlled trial evaluated a single SPG block for PDPH in patients with both intended and accidental dural punctures.

There was no statistically significant difference between active treatment and placebo for the primary outcome (median pain intensity in the upright position 30 minutes postintervention). Active rescue blocks were required in 65% of patients in each group, administered within an average of 1.4 hours for the active group and 1.5 hours for the placebo group. There was no statistically significant difference between active treatment and placebo for the number of patients requiring definitive treatment with an epidural blood patch. Additional studies, preferably RCTs, are needed to evaluate SPG blocks for treating PDPH. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **Practice Guidelines and Position Statements**

### **American Academy of Pain Medicine**

In 2022, the American Academy of Pain Medicine conducted a systematic review to develop practice recommendations for use of percutaneous interventional strategies for the preventive treatment of migraine. Sphenopalatine ganglion blocks received a weak recommendation for chronic migraine prevention based on a very low certainty of evidence. The only therapy evaluated in the guideline that received a strong recommendation for chronic migraine prevention was onabotulinumtoxinA.

### **American Headache Society**

The American Headache Society (AHS) Special Interest Section for Peripheral Nerve Blocks and Other Interventional Procedures cited the paucity of evidence for treatment of most headache disorders and cranial neuralgias, excluding cluster headaches.

The Institute for Clinical Systems Improvement's clinical guideline on "Diagnosis and treatment of headache" (2013) did not mention trigeminal nerve block as a therapeutic option.

An updated consensus statement for treating migraine was released in December 2018 by the American Headache Society.

Use evidence-based treatment at the first sign of a migraine attack. Use NSAIDs (including aspirin), nonopioid analgesics, acetaminophen, or caffeinated analgesic combinations for mild-to-moderate attacks and migraine-specific agents (triptans, dihydroergotamine) for moderate or severe attacks and mild-to-moderate attacks that respond poorly to NSAIDs or caffeinated combinations.

Use a nonoral option for select patients, including those with nausea or vomiting or those who have trouble swallowing.

Options for outpatient rescue include SC sumatriptan, DHE injection or intranasal spray, or corticosteroids. Inpatient options may include parenteral formulations of triptans, DHE, antiemetics, NSAIDs, anticonvulsants (e.g., valproate sodium and topiramate,



except in women of childbearing age who are not using reliable birth control), corticosteroids, and magnesium sulfate.

### **European Headache Society**

In 2019, the European Headache Foundation issued an update: Aides to management of headache in primary care (2<sup>nd</sup> edition) and this updated management guide does not mention the use sphenopalatine ganglion nerve block or any other types of nerve blocks in the treatment of headaches or trigeminal neuralgia.

### **Regulatory Status**

The Tx360 Nasal Applicator Device (Tian Medical, the Allevio SPG Nerve Block Catheter (JET Medical), and the 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 on efficacy but only notification of FDA prior to marketing. All 3 devices are used to apply local anesthetic intranasally.

## **PRIOR APPROVAL**

Not applicable

## **POLICY**

### **See Related Medical Policies**

- [07.01.66 Ablative Treatments for Occipital Neuralgia, Chronic Headaches and Atypical Facial Pain](#)
- [02.01.04 Biofeedback](#)

Sphenopalatine ganglion (SPG) block(s) are considered **investigational** for the treatment of migraines (acute or chronic) and/or other non-migraine headaches (to include severe acute headache of mixed etiologies, post dural puncture headache [PDPH]) because the evidence is insufficient to support a conclusion concerning the net health outcomes or benefits associated with this procedure.

Nerve block(s)/injection therapy of local anesthetic steroids or other agents to the stellate ganglion, supraorbital nerve, occipital nerve, or trigeminal nerve is considered **investigational** for the treatment of migraines (acute or chronic) and non-migraine headaches (to include severe acute headache of mixed etiologies) because the evidence is insufficient to support a conclusion concerning the net health outcomes or benefits associated with this procedure.

## **PROCEDURE CODES AND BILLING GUIDELINES**

To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 30999 Unlisted procedure, nose
- 64400 Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (i.e., ophthalmic, maxillary, mandibular)
- 64405 Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve
- 64505 Injection, anesthetic agent, sphenopalatine ganglion
- 64510 Injection, anesthetic agent; stellate ganglion (cervical sympathetic)
- 64999 Unlisted procedure, nervous system

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<b>POLICY HISTORY</b>		
<b>Date</b>	<b>Reason</b>	<b>Action</b>
July 2022	Annual Review	Policy Revised
July 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Renewed
July 2019	Annual Review	Policy Revised
August 2018	Annual Review	Policy Revised
August 2017	Annual Review	Policy Revised
August 2016	Annual Review	Policy Revised
September 2015	Annual Review	Policy Revised
October 2014	Annual Review	Policy Renewed
December 2013	Annual Review	New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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