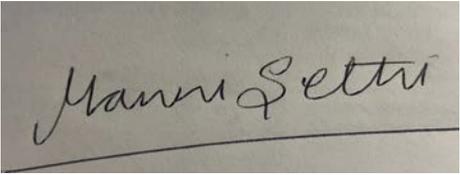


**Prior Authorization Review Panel
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First Community HealthChoices	Submission Date: 10/27/2023
Policy Number: ccp.1253	Effective Date: 5/2016 Revision Date: May 1, 2023
Policy Name: Sphenopalatine ganglion block injections for headache	
Type of Submission – Check all that apply: New Policy <input checked="" type="checkbox"/> Revised Policy* Annual Review – No Revisions Statewide PDL	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below: See tracked changes below.	
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Sphenopalatine ganglion block injections for headache

Clinical Policy ID: CCP.1253

Recent review date: 5/2023

Next review date: 9/2024

Policy contains: Bupivacaine, botulinum toxin, cluster headache, functional endoscopic sinus surgery, migraine headache, trigeminal neuralgia, sphenopalatine ganglion block.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' 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 Keystone First Community HealthChoices 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. Keystone First Community HealthChoices' 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. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Sphenopalatine ganglion block injections for headache are investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Sphenopalatine ganglion block neuro-stimulation.
- 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 (Charleston, 2016). Sphenopalatine ganglion blocks have been used to treat a variety of head pain disorders such as:

- 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 (Giaccari, 2021).

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 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 had been performed in European nations (Tepper, 2017).

Functional endoscopic sinus surgery, while not addressing a specific type of headache, is another condition for which sphenopalatine ganglion block has been more commonly used in recent years.

Sphenopalatine ganglion-based techniques for cluster headaches include block, stimulation, radiofrequency, stereotactic radiosurgery, and vidian neurectomy (Rosso, 2019).

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).

Findings

A position statement from the European Headache Foundation recommends sphenopalatine palatine block stimulation before deep brain stimulation in chronic cluster headaches (Martilletti, 2013), as does 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, including an American Academy of Neurology/American Headache Society 2019 guideline for treating migraines in children and adolescents (Oskoui, 2019).

An expert panel that reviewed 16 randomized controlled trials gave a weak recommendation for occipital nerve block with sphenopalatine block injections as a means of preventing migraine headaches (Barad, 2022).

A systematic review of 17 studies of refractory chronic and episodic cluster headaches compared various sphenopalatine ganglion treatments. The most successful procedure was block, which reported 76.5% (refractory chronic) and 87% (episodic) efficacy. Other approaches included radiofrequency (33% and 70.3%), and stimulation (55% and 71%) (Rosso, 2019).

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).

A systematic review of three studies, each between 10 and 17 subjects with cluster headaches, examined the use of botulinum toxin for the treatment of cluster headache. Each study found significant improvement in headache frequency as early as one week after treatment, but also found injections into the sphenopalatine ganglion may have an elevated rate of adverse events (Freund, 2020). A review of 489 sphenoganglion blocks performed 2015 – 2018 on patients age 6 – 26 years with migraine headache or status migrainosus found 100% technical success with significantly reduced average pain scores ($P < .0001$). Authors reported no immediate or acute complications and supported the treatment in refractory pediatric migraines to reduce intravenous medications, prolonged pain control, or hospital admission (Mousa, 2021).

A study of sphenopalatine block injections administered 310 times on 200 children with migraine headaches age 7 – 18 revealed that self-reported levels of pain declined more than two points on a 10-point scale within 10 minutes, along with a significant decrease in headache score (Dance, 2017).

A systematic review of 19 studies ($n = 221$ subjects with postdural puncture headache), including 97 given sphenopalatine nerve block injections, showed most subjects experience relief (71.4%, 85.7%, and 92.9% within 1, 24, and 48 hours), with no adverse effects (Giaccari, 2021).

A systematic 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. Authors state that long-term follow-up data is needed (Sanchez-Gomez, 2021).

Despite the clearly delineated targeted area and resultant effectiveness of pain relief when blocked; the optimal blocking method/technique has yet to be determined. Clinicians have developed invasive as well as non-invasive techniques but each one demonstrates varying rates and duration of pain reduction. 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 (Jeffery, 2021).

References

On March 20, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “sphenopalatine ganglion injection,” and “sphenopalatine ganglion block injection.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

7/2016: initial review date and clinical policy effective date: 10/2016

6/2017: Policy references updated.

5/2018: Policy references updated.

6/2019: Policy references updated. Policy Name changed to CCP.1253.

5/2020: We did not identify any new relevant publications.

5/2021: Policy references updated.

5/2022: Policy references updated.

5/2023: Policy references updated.