



Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Sphenopalatine Ganglion (SPG) Block

- Allevio SPG Nerve Block Catheter
- SphenoCath
- TX360

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	Billing Medicare for the SphenoCath® and Other Similar Devices (A55585)
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, Sphenocath Ganglion Block , for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

No review required at this time.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Sphenopalatine ganglion (SPG):

Robbins et al., 2016: The SPG is a triangular ganglion situated in the pterygopalatine fossa (PPF) on the medial wall. It is suspended by two branches of the maxillary nerve. The SPG received 3 inputs from the sensory, sympathetic, & parasympathetic fibers which innervate the face and head. The parasympathetic fibers originate from the superior salivatory nucleus (SSN) in the brainstem. The SSN stimulates the SPG whose activation results in pain/headache through several mechanisms (production of vasoactive peptides, neurogenic inflammation, vasodilation). SPG activation is therefore responsible for the clinical symptoms seen in migraine headaches, cluster headaches, trigeminal-mediated headaches and other headaches. Treatments that block SPG may alleviate headaches.

SPG block:

There are three methods to complete SPG block: transnasal, transoral, and transcutaneous blocks (Alexander et al., 2020). Some of these approaches utilized intranasal devices. Intranasal devices use catheter to perform

sphenopalatine ganglion blockade. There are several devices including Sphenocath, Allevio SPG nerve block catheters, and Tx360 nasal applicator. Sphenocath is the focus of the current review.

Sphenocath:

Sphenocath is composed of an external sheath in which there is a catheter with a preformed angle (<http://sphenocath.com/>). The device is introduced in the nasal cavity and inserted in the superior part of the middle nasal turbinate while the patient is in supine position with extension of the cervical spine. The procedure can be performed under fluoroscopy to locate the tip of the sheath. The anesthetic agent, 1-2 ml of 2% lidocaine is then administered by the catheter. After the procedure, the patient remains in supine position for 10 minutes (Robins et al., 2016). Sphenocath may prevent nasal mucosal irritation due to its flexibility and physical integrity (<http://sphenocath.com/>).

There are several indications for the procedure. However, the review focuses on the efficacy and safety of the procedure on migraine and trigeminal neuralgia. Contraindications consist of allergy to lidocaine, stenosis of nasal canal, inability to thread the catheter, and severe cardiac arrhythmia (Forrest et al., 2018).

Migraine:

Migraine is an attack of intermittent headache lasting four to 72 hours with or without aura. Fifteen percent (15%) of US population has migraine. Patients with migraine experience pain with visual disturbances (flashes, sparks, luminous hallucinations), photophobia, aura. Migraine can be precipitated by emotions and is associated with nausea and vomiting. Several medications including triptans, nonsteroidal anti-inflammatory drugs (NSAIDs), opiate-based analgesics, and ergotamine tartrate are available for the management of acute episodic and chronic migraine (Mwanburi et al., 2018).

Trigeminal neuralgia:

Trigeminal neuralgia (TN) is a severe, shock-like, paroxysmal pain in the face along the divisions of the trigeminal nerve. It can be precipitated by touching the face. Its management consists of sodium channel blockers and neurosurgical intervention (second line treatment) (Maarbjerg et al., 2017).

Medical Technology Assessment Committee (MTAC)

Sphenopalatine ganglion block using Sphenocath device for migraine and trigeminal neuralgia

Date: 01/11/2021

Evidence Conclusion:

- No studies comparing Sphenocath device to other methods performing SPG block were identified. The studies reviewed were of very low quality.
- There is insufficient evidence to determine the efficacy and safety of sphenopalatine ganglion block using Sphenocath device in patients with migraine.
- There is insufficient evidence to determine the efficacy and safety of SPG block using Sphenocath device in patients with trigeminal neuralgia.

Articles:

PubMed was searched through December 3, 2020 with the search terms ((migraine) AND (sphenopalatine ganglion block OR sphenopalatine block OR SPG OR sphenopalatine ganglion)) AND (Sphenocath) with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. RCTs, meta-analysis of RCTs, observational studies were included in the search. Regarding trigeminal neuralgia, search terms included: sphenopalatine ganglion block AND trigeminal neuralgia. Four studies were reviewed. Clinicaltrials.gov was also searched and found one study with no results (NCT03666663). See [Evidence Table](#).

The use of Sphenopalatine ganglion block using Sphenocath device for migraine and trigeminal neuralgia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Medicare and Non-Medicare: No review required – may be submitted with the following code(s)

CPT® or HCPC Codes	Description
64999	Unlisted procedure, nervous system

Non-Medicare: No review required

CPT® or HCPC Codes	Description
64505	Injection, anesthetic agent; sphenopalatine ganglion

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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03/02/2021	03/02/2021 ^{MPC} , 03/01/2022 ^{MPC} , 03/07/2023 ^{MPC}	

^{MPC} Medical Policy Committee

Revision History	Description
03/02/2021	MPC approved to adopt coverage Sphenopalatine Ganglion (SPG) Block