

Policy: MP318

Section: Medical Benefit Policy

Subject: Sphenopalatine Ganglion Block for Headache

Applicable line of business:

Commercial	x	Medicaid	x
Medicare	x	ACA	x
CHIP	x		

I. Policy: Sphenopalatine Ganglion Block for Headache and Pain

II. Purpose/Objective:

To provide a policy of coverage regarding Sphenopalatine Ganglion Block for Headache and Pain

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children’s Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Sphenopalatine ganglion (SPG) nerve block via an intranasal topical anesthetic has been proposed as a treatment for chronic migraine and severe non-migraine headache. The SPG is located behind the bony structures of the nose and is linked to the trigeminal nerve, the primary nerve involved in headache disorders. The SPG has both autonomic and sensory nerves associated with pain perception. SPG blocks involve topical application of local anesthetic to mucosa overlying the SPG. It is proposed that local anesthetics in low concentrations could block the sensory fibers and reduce pain while maintaining autonomic function.

Delivery devices to apply the anesthetic medication including but not limited to the SphenoCath®, Tx360® Nasal Applicator, and the Allevio™ SPG Nerve Block Catheter are considered class I devices by the FDA and are exempt from 510(k) requirements. There is no requirement for submission of clinical data regarding efficacy in this classification - only a notification to the FDA prior to marketing the device.

EXCLUSIONS:

The Plan does **NOT** provide coverage for the use of sphenopalatine ganglion block in the treatment of headache or non-headache facial pain because it is considered **unproven**. Although the catheters used to administer the anesthetic agent are FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Sphenopalatine Ganglion Block for Headache

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

64999 Unlisted procedure, nervous system

64505 Injection, anesthetic agent; sphenopalatine ganglion

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Cady R, Saper J, Dexter K, et al. A double-blind, placebo-controlled study of repetitive transnasal sphenopalatine ganglion blockade with tx360 as acute treatment for chronic migraine. *Headache*. Jan 2015;55(1):101-116.

Cady RK, Saper J, Dexter K, et al. Long-term efficacy of a double-blind, placebo-controlled, randomized study for repetitive sphenopalatine blockade with bupivacaine vs. saline with the Tx360 device for treatment of chronic migraine. *Headache*. Apr 2015;55(4):529-542.

Sanders M, Zuurmond WW. Efficacy of sphenopalatine ganglion blockade in 66 patients suffering from cluster headache: a 12- to 70-month follow-up evaluation. *J Neurosurg*. Dec 1997;87(6):876-880.

Candido KD, Massey ST, Sauer R, et al. A novel revision to the classical transnasal topical sphenopalatine ganglion block for the treatment of headache and facial pain. *Pain Physician*. Nov-Dec 2013;16(6):E769-778.

Schaffer JT, Hunter BR, Ball KM, et al. Noninvasive sphenopalatine ganglion block for acute headache in the emergency department: a randomized placebo-controlled trial. *Ann Emerg Med*. May 2015;65(5):503-510.

Felisati G, Arnone F, Lozza P, et al. Sphenopalatine endoscopic ganglion block: a revision of a traditional technique for cluster headache. *Laryngoscope*. Aug 2006;116(8):1447-1450.

Pipolo C, Bussone G, Leone M, et al. Sphenopalatine endoscopic ganglion block in cluster headache: a reevaluation of the procedure after 5 years. *Neurol Sci*. Jun 2010;31 Suppl 1:S197-199.

Khan, S; Schoenen, J; Ashina, M. "Sphenopalatine ganglion neuromodulation in migraine: What is the rationale?" *Cephalalgia* 2014;34(5):382-391

Bratbak DF, Nordgard S, Stovner LJ, et al. Pilot study of sphenopalatine injection of onabotulinum toxin A for the treatment of intractable chronic cluster headache. *Cephalalgia*. 2016;36(6):503-09.

Ferrante, FM, Kaufman, AG, Dunbar, SA, Cain, CF, Cherukuri, S. Sphenopalatine ganglion block for the treatment of myofascial pain of the head, neck, and shoulders. *Reg Anesth Pain Med*. 1998;23(1):30-6.

Binfalah M, et al Successful Treatment of Refractory Trigeminal Neuralgia with Sphenopalatine Ganglion Block. *Neurology* 2018; 90 (15 Supplement)

Kwo Wei D, et al Sphenopalatine ganglion: block, radiofrequency ablation and neurostimulation - a systematic review. *J headache and Pain* 2017;18(118)

Zanella S, et al. Transnasal sphenopalatine ganglion blockade for acute facial pain: a prospective randomized case-control study. *European Review for Medical and Pharmacological Sciences* 2018; 22: 210-216

Krebs, K, Rorden, C, and Androulakis, XM. Resting State Functional Connectivity After Sphenopalatine Ganglion Blocks in Chronic Migraine With Medication Overuse Headache: A Pilot Longitudinal fMRI Study. *Headache*. 2018;58(5):732-743

Binfalah M, Alghawi E, Shosha E, Alhilly A, Bakhiet M. Sphenopalatine ganglion block for the treatment of acute migraine headache. *Pain Research and Treatment*. 2018:2516953.

Gupta, R., Fisher, K. & Pyati, S. Chronic Headache: a Review of Interventional Treatment Strategies in Headache Management. *Curr Pain Headache Rep* 2019;23:68

Slullitel A, Santos IS, Machado FC, Sousa AM. Transnasal sphenopalatine nerve block for patients with headaches. *Journal of clinical anesthesia*. 2018;47:80-81.

Crespi J, Bratbak D, Dodick D, et al. Measurement and implications of the distance between the sphenopalatine ganglion and nasal mucosa: a neuroimaging study. *J Headache Pain* 2018;19:14

Rosso C, Felisati G, Bulfamante A, Pipolo C. Cluster headache: crosspoint between otologists and neurologists-treatment of the sphenopalatine ganglion and systematic review. *Neurol Sci.* 2019;40(Suppl1):137-146

Jespersen MS, Jaeger P, Aegidius KL, et al. Sphenopalatine ganglion block for the treatment of postdural puncture headache: a randomised, blinded, clinical trial. *Br J Anaesth.* Jun 2020; 124(6): 739-747.

Barad M, Ailani J, Hakim SM, et al. Percutaneous Interventional Strategies for Migraine Prevention: A Systematic Review and Practice Guideline. *Pain Med.* Aug 11 2021.

Mousa MA, Aria DJ, Mousa AA, Schaefer CM, Temkit MHM, Towbin RB. Sphenopalatine ganglion nerve block for the treatment of migraine headaches in the pediatric population. *Pain Physician.* 2021;24(1):E111-E116.

Dwivedi P, Singh P, Patel TK, et al. Trans-nasal sphenopalatine ganglion block for postdural puncture headache management: a meta-analysis of randomized trials. *Braz J Anesthesiol.* Jul 06 2023.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/17

Revised: 11/20 (add general information); 11/25 (update Unproven language)

Reviewed: 11/18, 11/19, 11/21, 11/22, 11/23, 11/24

CMS UM Oversight Committee Approval: 12/23, 12/24, 2/26

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.