MEDICAL POLICY – 7.01.159
Sphenopalatine Ganglion Block for Headache

BCBSA Ref. Policy: 7.01.159
Effective Date: Aug. 1, 2017
Last Revised: Oct. 5, 2018
Replaces: N/A
RELATED MEDICAL POLICIES:
7.01.125 Occipital Nerve Stimulation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

The sphenopalatine ganglion (SPG) is a group of nerve cells behind the nose. This nerve bundle is linked to the trigeminal nerve, which has three branches going to the eye area and the upper and lower jaws. The trigeminal nerve is the main nerve linked to headache disorders. A new type of treatment has been proposed to address headaches and facial pain. In this treatment, a hollow tube (a catheter) is inserted into the nose and maneuvered near the SPG. Once the catheter is in place, anesthesia is applied. The goal is to use the anesthesia as a way to block pain signals. This treatment is unproven (investigational). Larger, high-quality studies are needed to determine how effective this treatment is in the long term and how it compares to standard treatment for severe acute, migraine, and cluster headaches.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
Sphenopalatine ganglion blocks are considered investigational for all indications, including but not limited to the treatment of migraines and non-migraine headaches.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Unlisted procedure, nervous system</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

### Related Information

N/A

### Evidence Review

**Description**

Chronic migraine and severe headaches are common conditions and the available treatments are not universally effective. A proposed treatment option is blocking the sphenopalatine ganglion (SPG) by accessing it intranasally and applying topical anesthetic to it. Several catheters approved by the Food and Drug Administration are available for the SPG blocking procedure.
Background

Headaches and Headache Treatments

Headaches are common neurologic disorders and are among the top reasons that patients seek medical care. Headaches affect approximately 50% of the general population in a given year and over 90% of people have a lifetime history of headache.¹ The two most common types of headache are tension-type headaches and migraines. Tension headaches have a prevalence of approximately 40%.² Diagnostic criteria include the presence of at least 2 of the following characteristics: bilateral headache location, nonpulsating pain, mild-to-moderate intensity, and headache not aggravated by physical activity.³ Migraines are the second-most common headache disorder, with a 1-year migraine prevalence of approximately 12% in the United States.² They are characterized by severe pain on 1 or both sides of the head, nausea, and, at times, disturbed vision. Migraines can be categorized by headache frequency, and by the presence or absence of aura. Chronic migraine is defined as attacks on at least 15 days per month for more than 3 months, with features of migraine on at least 8 days per month.³

Cluster headaches are less common than tension or migraine headaches, with an estimated prevalence of 0.1% of the population.² They are characterized by severe unilateral orbital, supraorbital, and/or temporal pain that also includes other symptoms in the eye and/or nose on the same side (eg, rhinorrhea, eyelid edema or drooping).

Treatment

A variety of medications are used to treat acute migraine episodes. They include medications taken at the onset of an attack to abort the attack (triptans, ergotamines) 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 (eg, relaxation, cognitive therapy) are used to manage migraine headache. Botulinum toxin type A injections are a U.S. Food and Drug Administration–approved treatment for chronic migraine.

Severe acute 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 Block**

Sphenopalatine ganglion (SPG) blocks are a proposed treatment option for chronic migraines and some severe non-migraine headaches. 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, the primary nerve involved in headache disorders. The SPG has both autonomic nerves, which in this case are associated with functions such as tearing and nasal congestion, and 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 blockade is to intranasally insert a 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 and reaches the SPG. Some form of SPG blocking procedure has been used for many years. Originally, SPG blocks were done by inserting a cotton-tipped applicator dabbed with local anesthetic into the nose; this technique may be less accurate and effective than the currently proposed procedure. Another variation is to insert a needle into the cheek and inject local anesthetic but this no longer appears to be used because it is more invasive and can be painful. Neurostimulation of the SPG and SPG blockade with radiofrequency lesioning have been used outside of the United States, but these treatments are not cleared or approved by FDA.

Three catheter devices are commercially available in the United States for performing SPG blocks. The catheters have somewhat different designs but all are attached to syringes that contain local anesthetic. The catheters are inserted intranasally and, once in place, the local anesthetic is applied through the catheter. With 2 of the 3 commercially available catheters (the SpenoCath®, Allevio™), patients are positioned on their back with their nose pointed vertically. With the Tx360® device, patients remain seated.

The company marketing the Tx360® device proposes its use in the context of the MiRx™ protocol. This 2-part protocol 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 of a number of approaches such as physical therapy, ergonomic modifications, massage, and dietary recommendations.
The optimal number and frequency of SPG treatments is unclear. Information from the American Migraine Foundation suggests that the procedure can be repeated as often as needed to control pain.\(^5\) A randomized controlled trial (RCT) has described a course of treatment for migraines consisting of SPG blocks twice a week for 6 weeks (total, 12 treatments).

SGB blocks are proposed for both short- and long-term treatment of headaches and migraines. When used in the emergency setting in patients with severe acute headaches, the goal of treatment is to abort the current headache while the patient is in the emergency department. In the RCT that provided a 6-week course of treatment with SPG blocks for chronic migraine (mentioned above), short-term outcomes were assessed up to 24 hours after each treatment, and the duration and frequency of chronic migraines were assessed at 1 and 6 months after the course of treatment.

**Summary of Evidence**

For individuals who have chronic migraine who receive sphenopalatine ganglion (SPG) block(s), the evidence includes a randomized controlled trial (RCT) and a case report. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The randomized trial evaluated a regimen of 12 SPG blocks over 6 weeks and was double-blind and placebo-controlled. The trial found significantly greater short-term (up to 24 hours) benefits from active treatment than from placebo. There were no significant longer term effects (ie, 1 and 6 months after 12 treatments), although the trial was underpowered to detect longer term efficacy. Given that SPG blocks are being proposed as a preventive therapy for chronic migraines, evidence demonstrating reduced migraine frequency, severity, or other objective outcomes from robust trials is still needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have severe acute headache treated in the emergency setting who receive SPG block(s), the evidence includes 1 RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The randomized, double-blind, placebo-controlled trial evaluated a single SPG block for severe acute headache of mixed etiologies. There was no statistically significant difference between active treatment and placebo for the primary outcome (pain reduction 15 minutes postintervention). The trialists did not collect pain data again until 24 hours posttreatment, at which time significantly more patients were headache-free in the active treatment arm than in the placebo arm. Additional studies, preferably RCTs, are needed to determine whether SPG blocks are an effective treatment in the emergency setting. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have cluster headache who receive SPG block(s), the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two small case series, both of which evaluate an approach for intranasal SPG blocks that differ from the intervention currently available in the United States, were identified. In these series, 40% to 50% of patients experienced complete symptom relief for a variable length of time and about 20% had treatment-related complications. However, it is not clear from these series the degree to which the procedures differ in safety and efficacy from an intranasal SPG block using a device cleared by the Food and Drug Administration. Additional studies, preferably RCTs, are needed to evaluate SPG blocks for treating cluster headaches. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>NCT02365909 Study Evaluating Sphenopalatine Ganglion Block (SPGB) for Treatment of Postdural Puncture Headache (PDPH)</td>
<td>30</td>
<td>Dec 2017</td>
</tr>
<tr>
<td></td>
<td>NCT02090998 Sphenopalatine Ganglion Nerve Block vs. Elavil for Treatment of Transformed Migraines</td>
<td>200</td>
<td>May 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Practice Guidelines and Position Statements

No guidelines or statements were identified.
Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

The Tx360® Nasal Applicator (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 numbing medication intranasally.

References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/01/17</td>
<td>New Policy, approved July 18, 2017, add to Surgery section. Policy created with literature review through March 23, 2017. Sphenopalatine ganglion blocks are considered investigational for all indications, including but not limited to the treatment of migraines and non-migraine headaches.</td>
</tr>
<tr>
<td>09/12/18</td>
<td>Coding update, added CPT code 64505.</td>
</tr>
<tr>
<td>10/05/18</td>
<td>Coding updated, removed CPT code 64505.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination Is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan Ilyan. Avi sila a kapab genyen enfòmasyon enpòtan konsënan aplikasyon w lan oswa konsefan kouvéti asirans lan atrave Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan seten da setim pou ou ka kete kouvéti asirans sante t l oswa pou yo ka ede w akav depans yo. Se dwa w pou resewaa enfòmasyon sa a ak asistans nan lang ou paale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaa ket naglaon iti Napateg nga Impomarsion. Daytoy a pakdaa mabalini nga adda ket naglaon iti napateg nga impomarsion maiyanggep iti aplikasyon ko coverage babaen iti Premera Blue Cross. Daytoy ket mabalini diig importanta a pelsa iti daytoy a pakdaar. Mabalini nga adda numa numbenga iti aramidenyo nga adda sakkab dagiti partikular a na tauling nga adda kawun tapno mapagtalaniedy ko coverage ti salun ayto nga tulog kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impomarsion ken tulog ti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

中文 (Chinese): 本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要的日期。您可能需要在截止日期之前採取行動，以保留您們的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

037338 (07-2016)
Japanese (Japanese):
この通知には重要な情報が含まれています。この通知には、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれている場合があります。この通知には記載されている可能性がある重要な日付をご確認ください。健康保険料や料金を維持するには、特定の期限内に行行動を取消されない場合があります。ご希望の言語による情報とサービスが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 거래 Premera Blue Cross를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 거래는 경우 의문서를 제외하거나 비용을 절약하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 거래 관련 정보는 거래의 만족 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)로 전화하십시오.

Română (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Esperanto (Esperanto):
Tiu notifo konsistas el gravaj informoj. Tiu notifo povas konsistigi gravajn informojn pri ĉiujn demandoj kaj ekziston de Premera Blue Cross. Ĉiujn informojn povas recevi libere kaj oni povas nomigi dumneavusajn ĉiujn informojn kaj helpon en la ĉiujn lingvoj. 800-722-1471 (TTY: 800-842-5357).

Polski (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Тиếng Việt (Vietnamese):

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвініть за номером телефону 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อมูลสิ่งสำคัญ ประกาศนี้มีข้อมูลสิ่งสำคัญเกี่ยวกับการขอรับการช่วยเหลือจากภายนอกสุขภาพของ Premera Blue Cross และผู้มีสิทธิ์ในกรณีที่คุณจะต้อง ดำเนินการในกำหนดเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่คุณมีสิทธิ์ใช้ โปรดติดต่อ Premera Blue Cross ที่ 800-722-1471 (TTY: 800-842-5357).