MEDICAL POLICY – 7.01.139
Peripheral Subcutaneous Field Stimulation

Introduction

Peripheral subcutaneous field stimulation (PSFS) uses small amounts of electricity to try to treat pain. Small electrodes are placed under the skin near the area of pain. The electrodes are connected by wires to a battery pack that generates electrical signals. The generator is usually also placed under the skin. The goal is to use small bursts of electricity to interrupt the pain signals carried by the nerves. PSFS is unproven (investigational). Studies comparing PSFS with other forms of pain treatment are needed to find out how well PSFS works for chronic pain.

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

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral subcutaneous field stimulation</td>
<td>Peripheral subcutaneous field stimulation is investigational.</td>
</tr>
</tbody>
</table>
Citing

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>64999</td>
</tr>
<tr>
<td>HCPCS</td>
<td>L8679</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

Peripheral subcutaneous field stimulation (PSFS) is a form of neuromodulation intended to treat chronic neuropathic pain. Applications of PSFS being evaluated are craniofacial stimulation for headache/migraine, craniofacial pain, or occipital neuralgia. PSFS is also being investigated for low back pain, neck and shoulder pain, inguinal and pelvic pain, thoracic pain, abdominal pain, fibromyalgia, and postherpetic neuralgia.
Background

**Chronic Pain**

Chronic, non-cancer pain is responsible for a high burden of illness. Common types of chronic pain are lumbar and cervical back pain, chronic headaches, and abdominal pain. All of these conditions can be challenging to treat.

**Treatment**

Medications are typically the first-line treatment for chronic pain, and several classes of medications are available. These include analgesics (opioid and non-opioid), antidepressants, anticonvulsants, and muscle relaxants. There are also a variety of non-pharmacologic treatments including physical therapy, exercise, cognitive-behavioral interventions, acupuncture, chiropractic, and massage.

Neuromodulation is another form of non-pharmacologic therapy that is usually targeted toward patients with chronic pain that is refractory to other modalities. Some forms of neuromodulation, such as transcutaneous electrical nerve stimulation and spinal cord stimulation (SCS), are established methods of chronic pain treatment. Peripheral nerve stimulation, which involves placement of an electrical stimulator on a peripheral nerve, is also used for neuropathic pain originating from peripheral nerves.

**Peripheral Subcutaneous Field Stimulation**

Peripheral Subcutaneous Field Stimulation (PSFS; also called peripheral nerve field stimulation or target field stimulation) is a modification of peripheral nerve stimulation. The objective of PSFS is to stimulate the region of affected nerves, cutaneous afferents, or the dermatomal distribution of the nerves, which then converge back on the spinal cord. Combined SCS and PSFS is also being evaluated.

Similar to SCS or peripheral nerve stimulation, permanent implantation is preceded by a percutaneous stimulation trial with at least 50% pain reduction. Currently, there is no consensus regarding the indications for PSFS. Criteria for a PSFS trial may include a clearly defined, discrete focal area of pain with a neuropathic or combined somatic/neuropathic pain component with characteristics of burning and increased sensitivity, and failure to respond to other conservative
treatments including medications, psychological therapies, physical therapies, surgery, and pain management programs.

The mechanism of action in PSFS is unknown. Theories include an increase in endogenous endorphins and other opiate-like substances; modulation of smaller A delta and C fibers by stimulated large-diameter A beta fibers; local stimulation of nerve endings in the skin; local anti-inflammatory and membrane depolarizing effect; or a central action via antegrade activation of A beta nerve fibers. Complications of PSFS include lead migration or breakage and infection of the lead or neurostimulator.

**Summary of Evidence**

The evidence for peripheral subcutaneous field stimulation in individuals who have chronic neuropathic pain includes 1 RCT, 1 nonrandomized comparative study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life and treatment-related morbidity. The single RCT, which used a crossover design, did not compare PSFS to alternatives. Rather, this study compared different methods of PSFS. For all patients, 24 of 30 patients (80%) had at least 50% reduction in pain with any type of PSFS. However, since the RCT did not include a sham group or comparison with a different active intervention, this study offers little evidence for efficacy beyond that of a prospective, uncontrolled study. In addition, case series are insufficient to evaluate pain outcomes due to the variable nature of pain and the subjective nature of the outcome measures. Prospective controlled trials comparing PSFS with placebo or alternative treatment modalities are needed to determine the efficacy of this treatment for chronic pain. 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><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISRCTN53432663</td>
<td>A randomised, patient-assessor blinded, sham-controlled trial of external non-invasive peripheral nerve stimulation for chronic neuropathic pain following peripheral nerve injury (EN-PENS trial)</td>
<td>75</td>
<td>Aug 2019</td>
</tr>
<tr>
<td>NCT02893267</td>
<td>Multimodal Treatment for Hemiplegic Shoulder Pain</td>
<td>132</td>
<td>Dec 2021</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

Practice Guidelines and Position Statements

In 2013 the National Institute for Health and Care Excellence issued guidance on PSFS.7 The guidance indicated:

Current evidence on the efficacy of peripheral nerve-field stimulation (PNFS) for chronic low back pain is limited in both quantity and quality, and duration of follow-up is limited. Evidence on safety is also limited and there is a risk of complications from any implanted device. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

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

No devices have been approved by the U.S. Food and Drug Administration (FDA) specifically for PSFS. PSFS as an off-label use of SCS devices has been approved by FDA for the treatment of chronic pain.
References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/13/13</td>
<td>New policy. Policy created with literature search through February 13, 2013; considered investigational.</td>
</tr>
<tr>
<td>05/12/14</td>
<td>Annual Review. Policy updated with literature review through February 19, 2014. References 1, 2, 4, 7 added; others renumbered/removed. Policy statement unchanged.</td>
</tr>
<tr>
<td>05/27/15</td>
<td>Annual Review. Policy updated with literature review through February 22, 2015; no references added; reference 2 updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>01/29/16</td>
<td>Minor update. Added HCPCS code L8679.</td>
</tr>
<tr>
<td>07/01/16</td>
<td>Annual Review, approved June 14, 2016. Policy updated with literature review through February 12, 2016; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Coding update, removed CPT codes 0282T, 0283T, 0284T, and 0285T as the codes were terminated 1/1/17.</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). ©2018 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).

Arabic (Arabic):
يحيى هذا الإشعار معلومات هامة. قد يحيى هذا الإشعار معلومات مهمة دافئة أو ماسمية التي تزود الأفراد على خلافهم من خلال Premera Blue Cross. من الممكن أن تكون هناك ترجمات تم ترجمتها بطلاقة في هذا الإشعار. قد تحتاج إعداد إجراء في ترجمة واحدة للعديد من قضايا التحليل أو غير العامة في السكن عالية. يحكي كل الحصول على هذه المعلومات والمساعدة بشكل دقيق دون تكلفة إضافية. إتصل بـ 800-722-1471 (TTY: 800-842-5357).

中文 (Chinese):
本通知有重要的讯息。本通知可能对您透过 Premera Blue Cross 提交的申请或保险的重要讯息。本通知可能有重要日期。您可能需要在截止日期之前采取行动，以保留您的健康保险或者费用补贴。您有权利免费以您的母语得到本讯息和帮助。请拨电话 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Deutsche (German):

Italiano (Italian):
Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagkakatulungan sa Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa at lihim kaya't maaaring nangyari ang mahalagang impormasyon na ito. Maaaring may mga petsa dito sa paunawa na ito kaya't maaaring nangyari ang mahalagang impormasyon na ito. Untuk itu, silakan hubungi 800-722-1471 (TTY: 800-842-5357).

Thai (Thai):
ประกาศนี้มีข้อต้องคำนึงที่สำคัญเกี่ยวกับการขอรับการรักษาด้วยการประกันสุขภาพของคุณ Premera Blue Cross และคุณจะต้องทราบว่าคุณควรจะดูวันที่ที่สำคัญในคำประกาศนี้เพื่อที่จะสามารถตัดสินใจได้ว่าคุณจะต้องทำสิ่งใดเพื่อการรักษาของคุณ ในกรณีที่คุณต้องการความช่วยเหลือต่อไปตามคำประกาศนี้ โปรดติดต่อกับ 800-722-1471 (TTY: 800-842-5357).

Ukrainian (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливі інформації про ваше звернення від страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані в цьому повідомленні. Існує можливість, 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. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Vietnamese (Vietnamese):

日本語 (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情報が重要な日付をご確認ください。健康保険や保険サービスを維持するには、特定の期日に行動を取らないとならぬ場合があります。ご自身の言語による情報をサポート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。


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 указаны 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).