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.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral subcutaneous field stimulation</td>
<td>Peripheral subcutaneous field stimulation (eg. SPRINT® peripheral nerve stimulation system) is considered investigational.</td>
</tr>
</tbody>
</table>
## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</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 and 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, noncancer 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

Pharmacologic agents are typically the first-line treatment for chronic pain, and several classes of medications are available. They include analgesics (opioid and non-opioid), antidepressants, anticonvulsants, and muscle relaxants. A variety of nonpharmacologic treatments also exist, including physical therapy, exercise, cognitive-behavioral interventions, acupuncture, chiropractic, and massage.

Neuromodulation is another form of nonpharmacologic therapy that is usually targeted toward patients with chronic pain refractory to other modalities. Some forms of neuromodulation, such as transcutaneous electrical nerve stimulation and spinal cord stimulation, 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) is a modification of peripheral nerve stimulation. In PSFS, leads are placed subcutaneously within the area of maximal pain. 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 spinal cord stimulation plus PSFS is also being evaluated.

Similar to spinal cord stimulation or peripheral nerve stimulation, permanent implantation is preceded by a percutaneous stimulation trial with at least 50% pain reduction. Currently, there is no consensus on the indications for PSFS. Criteria for a trial of PSFS 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 nerve 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

For individuals with chronic neuropathic pain who receive PSFS, the evidence includes a randomized controlled trial, a nonrandomized comparative study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single randomized controlled trial, which used a crossover design, did not compare PSFS with alternatives. Rather, it compared different methods of PSFS. Among trial participants, 24 (80%) of 30 patients had at least 50% reduction in pain with any type of PSFS. However, because the randomized controlled trial did not include a sham group or comparator with a different active intervention, this trial offers little evidence for efficacy beyond that of a prospective, uncontrolled study. Case series are insufficient to evaluate pain outcomes due to the variable nature of pain and the subjective nature of pain outcome measures. Prospective controlled trials comparing PSFS with placebo or alternative treatment modalities are needed to determine the efficacy of PSFS 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

| NCT No.       | Trial Name                                                                 | Planned Enrollment | Completion Date |
|---------------|-----------------------------------------------------------------------------|--------------------|----------------|---------------|
| **Ongoing**   |                                                                             |                    |                |               |
| ISRCTN53432663| 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) | 75                 | Aug 2019       |               |
| NCT02893267   | Multimodal Treatment for Hemiplegic Shoulder Pain                           | 132                | Dec 2021       |               |
| NCT03783689a  | The SNAP trial: SPRINT Peripheral Nerve Stimulation for the treatment of neuropathic post-amputation pain in a randomized, double-blinded, placebo-controlled multicenter trial | 126                | Oct 2022       |               |

NCT: national clinical trial
ISRCTN: International Standard RCT Number

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence issued guidance (2013) on peripheral subcutaneous field stimulation for chronic low back pain which stated⁷:

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.

Medicare National Coverage

There is no national coverage determination.
Regulatory Status

In July 2018, the SPRINT Peripheral Nerve Stimulation System (SPR Therapeutics, Inc) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K181422). FDA determined that this device was substantially equivalent to existing devices for use in pain management. PSFS is also an off-label use of spinal cord stimulation devices that have been approved by the Food and Drug Administration for the treatment of chronic pain.

References


<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>
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<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>
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<tr>
<td>01/29/16</td>
<td>Minor update. Added HCPCS code L8679.</td>
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<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>
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</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). ©2019 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 S09F, 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):
يكون هذا الإشعار معلومات هامة. قد يكون هذا الإشعار معلومات مهمة لبعضكم. قد تكون هناك تراخيص مهمة في هذا الإشعار. قد تتحاج للاطلاع على تراخيص منفصلة على تراخيص الصحية أو الخدمات. قد تكون هناك حقوق أخرى إلى تلك الخدمات. يفضل الاتصال 800-722-1471 (TTY: 800-842-5357).

Chinese (Chinese):
本通知有重要的信息。本通知可能有关於您透过 Premera Blue Cross 提交的申请或保险的重要讯息。本通知内可能有重要日期，您可能需要在截止日期之前採取行动。以保留您的健康保险或费用补贴。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).

Italiano (Italian):

Oromoo (Cushite):

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmason Enpòtan ladann. Avi sila a kapab genyen enfòmason enpòtan konsënan aplikasyon w lan oswa konsënan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewa enfòmason sa a ak asistans nan lang ou pale 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 Impomarsan. Daytoy a pakdaa mabalina nga adda ket naglaon iti napatek nga impomarsan, maipanggep iti aplikasyowo yenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalina dagiti importante a pelsa iti daytoy a pakdaar. Mabalina nga adda rumbenga nga aramidenyo nga adda sabbay dagiti partikular to naituding nga aldaw tapno mapagtalainedyo ti coverage ti salun-atyo yenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impomarsan ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag ti numero nga hoo 800-722-1471 (TTY: 800-842-5357).

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 nagalaman ng mahalagang impormasyon. Ang paunawa na ito ay nagaral agad sa iyong aplikasyon o pag-asa sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring ito ay maaaring naglalaman ng mahalagang impormasyon.

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Español (Spanish): 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).

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