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 (eg, SPRINT® peripheral nerve stimulation system) is considered investigational.</td>
</tr>
</tbody>
</table>
### Coding

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

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### 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 therapeutic massage.

Neuromodulation, another form of nonpharmacologic therapy, 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 trial of percutaneous stimulation 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 (RCT), a 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 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

<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>May 2020</td>
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<tr>
<td>NCT02893267</td>
<td>Multimodal Treatment for Hemiplegic Shoulder Pain</td>
<td>132</td>
<td>Dec 2021</td>
</tr>
<tr>
<td>NCT03783689&lt;sup&gt;a&lt;/sup&gt;</td>
<td>The SNAP trial: SPRINT Peripheral Nerve Stimulation for the treatment of neuropathic post-amputation pain in a randomized, double-blinded, placebo-controlled multicenter trial</td>
<td>126</td>
<td>Oct 2022</td>
</tr>
</tbody>
</table>

NCT: national clinical trial  
ISRCTN: International Standard RCT Number  
<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

**National Institute for Health and Care Excellence**

In 2013, the National Institute for Health and Care Excellence (NICE) issued guidance on peripheral subcutaneous field stimulation for chronic low back pain which stated<sup>7</sup>:

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). The 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


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>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</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>
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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>
</tr>
</tbody>
</table>

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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

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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 S909, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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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):


中文 (Chinese):

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Oromo (Cushite):


Deutsche (German):


Illoko (Ilocano):

Daytoy a Pakdaa kat naglao iti Napateg nga Impormasion. Daytoy a pakdaa mabalain nga adda kat naglao iti napateg nga impormasion maijangeppi aipiakyayon ngoy coverage babaen iti Premera Blue Cross. Daytoy ket mabalain dagiti importante a pelta iti daytoy a pakdaa. Mabalain nga adda rumbang nga aramidenyon nga addang sakbay dagiti partikular a naituding nga alabaw tapno mapagalatendiy a coverage ti salan-ayyo worthy tungon kadagiti gastos. Adda karbenganyon a mangala iti daytoy nga impormasion ken tungon ti bukodyo a pagasagao nga awan ti bayadanyon. Turawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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Este aviso contiene información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claras 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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800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อความสำคัญ ประกาศนี้มีข้อความสำคัญเกี่ยวกับการขอรับการช่วยเหลือจากสุขภาพของคุณ Premera Blue Cross และการมีส่วนร่วมในการป้องกันคุณ หากคุณต้องการข้อมูลเพิ่มเติมเกี่ยวกับสิทธิ์ของคุณในการช่วยเหลือจากสุขภาพของคุณ คุณควรติดต่อ Premera Blue Cross ที่ 800-722-1471 (TTY: 800-842-5357).

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