Introduction

Radiofrequency ablation (RFA) is a procedure that has been proven to treat certain kinds of pain in specific areas of the body. A radio wave produces an electrical current, which then heats up and destroys a small area of nerves. The nerves are unable to send pain signals to the brain. RFA has been tried as a way to limit or stop pain in feet caused by plantar fasciitis and in the knees caused by wear-and-tear arthritis. The studies looking at RFA in these areas only studied a few dozen people. They also followed the patients for only a few weeks after treatment. There is not enough information from clinical studies to be certain that this works for foot and knee pain. For this reason, RFA is considered investigational (unproven) when used in these areas.

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.
Radiofrequency ablation of peripheral nerves to treat nerve pain, including but not limited to pain associated with plantar fasciitis or knee osteoarthritis, is considered investigational.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>64640</td>
<td>Destruction by neurolytic agent; other peripheral nerve or branch</td>
</tr>
<tr>
<td>64999</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

Radiofrequency ablation of nerves has been proposed as a treatment for several different types of pain. It has been used to treat a number of clinical pain syndromes such as trigeminal neuralgia, cervical and lumbar pain, and headache syndromes.
Background

**Plantar Fasciitis**

Plantar fasciitis is a common cause of foot pain in adults, characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some patients the pain may persist, impairing activities of daily living. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. The exact etiology of plantar fasciitis is unclear, although repetitive injury is suspected. Heel spurs are a common associated finding, although it has never been proven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population. Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization of running and jumping, heel cups, and nonsteroidal anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to 1 year in some cases.

**Knee Osteoarthritis**

Knee osteoarthritis is common, costly, and a cause of substantial disability. Among U.S. adults, the most common causes of disability are arthritis and rheumatic disorders. Treatment for osteoarthritis of the knee aims to alleviate pain and improve function. However, most treatments do not modify the natural history or progression of osteoarthritis and are not considered curative. Nonsurgical modalities that are used include exercise; weight loss; various supportive devices; acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen; nutritional supplements (glucosamine, chondroitin); and intra-articular viscosupplements. Corticosteroid injection may be considered when relief from nonsteroidal anti-inflammatory drugs is insufficient or the patient is at risk from gastrointestinal adverse effects. If symptom relief is inadequate with conservative measures, invasive treatments may be considered. Operative treatments for symptomatic OA of the knee include arthroscopic lavage and cartilage débridement, osteotomy, and, ultimately, total joint arthroplasty. Surgical procedures intended to repair or restore articular cartilage in the knee (eg, abrasion arthroplasty, microfracture techniques, autologous chondrocyte implantation) are appropriate only for younger patients with focal cartilage defects secondary to injury and are not addressed in this evidence review.
**Nerve Radiofrequency Ablation**

Nerve radiofrequency ablation (RFA) is a minimally invasive method that involves the use of heat and coagulation necrosis to destroy nerve tissue. A needle electrode is inserted through the skin and into the tissue around the nerve to be ablated. A high-frequency electrical current is applied to the target tissue which heats the nerve, causing coagulation necrosis and destruction of the nerve. It is theorized that the thermal lesioning of the nerve destroys peripheral sensory nerve endings, resulting in the alleviation of pain. Cooled radiofrequency (RF) treatment is a variation of nerve RFA using a special device that applies more energy at the desired location without excessive heat diffusing beyond the area, causing less tissue injury away from the nerve. The goal of ablating the nerve is the same.

For the indications assessed in this evidence review, nerve RFA should be distinguished from RF energy applied to areas other than the nerve to cause tissue damage. Some patients have been treated for plantar fasciitis with a fasciotomy procedure using a RF device. This procedure does not ablate a specific nerve.

Nerve RFA is also distinguished from pulsed RF treatment, which has been investigated as a treatment for different types of pain. The mechanism of action of pulsed RF treatment is uncertain, but it is thought not to destroy the nerve. If it does produce some degree of nerve destruction, it is thought to cause less damage than standard RFA. Some studies refer to pulsed RF treatment as ablation.

**Summary of Evidence**

For individuals who have plantar fasciitis who receive radiofrequency ablation of the peripheral nerves, the evidence includes case series studies and a randomized controlled trial. Relevant outcomes include symptoms and functional outcomes. The case series generally have small sample sizes, and many have methodologic deficiencies such as retrospective assessment of pain. The single randomized controlled trial evaluated only 17 patients, and randomized outcomes could only be assessed out to 4 weeks posttreatment. Although the studies report that radiofrequency ablation reduces heel pain, the quality of the evidence is poor. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have knee osteoarthritis who receive radiofrequency ablation of the peripheral nerves, the evidence includes case series and a randomized controlled trial. Relevant outcomes include symptoms and functional outcomes. The method of radiofrequency treatment varied between studies. Some case series showed improvement in symptoms with treatment.
The single randomized trial had a small sample size (N=38) and assessed outcomes out to 12 weeks. Although this trial showed improvement in pain at 12 weeks, these results do not support any conclusions about treatment efficacy. 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>NCT02294864</td>
<td>A Controlled Comparison of Pulsed Radiofrequency Vs Physical Therapy on Treating Chronic Knee Osteoarthritis</td>
<td>50</td>
<td>Apr 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT02260869</td>
<td>Efficacy of Cooled and Monopolar Radiofrequency Ablation of the Geniculate Nerves for the Treatment of Chronic Osteoarthritic Knee Pain</td>
<td>102</td>
<td>July 2018</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02242513</td>
<td>Ultrasound-guided Pulsed Radiofrequency for Plantar Fasciitis</td>
<td>36</td>
<td>July 2016 (completed)</td>
</tr>
<tr>
<td>NCT02343003*</td>
<td>Nerve Ablation by Cooled Radiofrequency Compared to Corticosteroid Injection for Management of Knee Pain</td>
<td>144</td>
<td>Mar 2017 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial  
NR: not reported

Practice Guidelines and Position Statements

The American College of Foot and Ankle Surgeons issued a guideline on the treatment of heel pain in 2010. Bipolar radiofrequency is listed as a third tier option for patients who have failed other treatments. It was given a grade C recommendation, meaning that this treatment option is supported by either conflicting or level IV (expert opinion) evidence.
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

A number of radiofrequency (RF) generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2005, the SInergy® (Kimberly Clark/Baylis, Irving, TX), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is with a RF generator to create RF lesions in nervous tissue. FDA product code: GXD.

In September 2011, NeuroTherm® NT 2000 (NeuroTherm, Wilmington, MA) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in lesioning neural tissue. Existing predicate devices included the NeuroTherm NT 1000, Stryker Multi-Gen, and Cosman G4 RF Generator.

References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/01/16</td>
<td>New Policy, approved June 14, 2016. Radiofrequency ablation of peripheral nerves to treat nerve is considered investigational.</td>
</tr>
<tr>
<td>11/01/17</td>
<td>Annual Review, approved October 19, 2017. Policy updated with literature review through July 20, 2017; no references added. Policy statement clarified; added “including but not limited to”.</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)

Complaint forms are available at

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):

يحمل هذا الإشعار معلومات مهمة. قد يحتوي هذا الإشعار على معلومات يمكن أن تؤثر على حقوقك. في حالة ألقاك للإشعار، يرجى النجاح في قراءة النص باللغة العربية للتأكد من فهمك للنص. في حالتك، قد يكون لديك الحق في الحصول على مساعدة في فهم النص. اتصل بالهاتف لاستلام مساعدة في فهم النص.

Chinese (Chinese):

本通知有重要的讯息。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采取行动，以保留您的健康保险或费用补贴。您有权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 (Oromo):

_confirmation_ beeka.

French (French):


German (German):


Creole (Creole):


Italian (Italian):

Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero essere espressi date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.

Chamorro (Chamorro):

Daytuo a Pakdaak ket naglaon iñi Napateg nga Impomorsa. Daytuo a pakdaak mabalin nga adda ket naglaon iñi napateg nga impomorsa maipanggep iti aplekasyono weno coverage babaen iti Premera Blue Cross. Daytuo ket mabalin dagiti importante a pelsa iti daytuo a pakdaak. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw taba noun resewat nga adaw tetaa tagtisti nga bana. Tagtisti weno coverage w la kawa ati daytuo nga imposans no impomorsa w la kawa ati daytuo nga kawat a ng OMAP nga bana. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).
Premera Blue Cross is committed to providing information for those covered under Premera Blue Cross. If you have questions, you may contact our Customer Service at 800-722-1471 (TTY: 800-842-5357) or visit us online at prep.org.

This alert contains important information.

Talvez seja necessário que você tome providências dentro de um prazo específico.

Este aviso contém informações importantes.

 הזן (Lao):
 CPFsที่จัดที่มีข้อมูลที่ซับซ้อนและข้อมูลที่เกี่ยวข้องอยู่ในไม้สักสัมพันธ์กับPremera Blue Cross. คุณอาจติดต่อเราได้ที่ 800-722-1471 (TTY: 800-842-5357)หรือเข้าเว็บไซต์ของ chúng tôiที่ prep.org.

This alert contains important information.

In the event that you are covered by Premera Blue Cross, you may contact our Customer Service at 800-722-1471 (TTY: 800-842-5357) or visit us online at prep.org.

Fa’sasomoa (Samoa):
Atou no i fale ai i lenei fa’asilasiaga ni fa’amatala e sili ona taua e tauta ona e malama malama ai o. O lenei fa’asilasiaga e fa sefoasoani e fa’amatala atoni ai i le i lufaga a le polokalame, Premera Blue Cross, ua e tau fa maou atau i i ai. Fa’amolemo, ia i iolo fa’alele i i aso fa’apito o’i o’i lenei fa’asilasiaga taua. Masolo o le’i ai ni feau e tauta ona e faiso a le’a i le aulale a le aso u’a le’ai i fale ai fa’asilasiaga ina ia i e i pea maou fafoasoani mai ai i le polokalame a le Malo o’lo o’i o’i ai. Olo o i iate o le aia taua e tauta atu i i lenei fa’asilasiaga ma lenei fa’matala e legalaga e le malama malama ai auona ma se tojiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claves 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):

ไทย (Thai):
ประกาศนี้มีข้อมูลสำคัญที่คุณควรรู้เกี่ยวกับการขอความช่วยเหลือในการรับฟรีไม่มีค่าใช้จ่ายของ Premera Blue Cross และคุณยินดีที่จะให้คุณได้รับข้อมูลและการช่วยเหลือในการเรียนรู้ภาษาที่คุณคิดว่าคุณต้องการ.

Polskie (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 e 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).

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 указаны ключевые даты. Вам, возможно, потребуется привезти к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. You have the right to obtain this information and assistance in your own language. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

乌克兰 (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує ймовірність того, що Вам буде здобуті перша кінцева стрічка 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).

Tiếng Việt (Vietnamese):
Thông báo này cung cấp thông tin quan trọng. Thông báo này có thể会影响您在Premera Blue Cross的投保状况，或者您有权获得有关这项保险的更多信息。您有权向Premera Blue Cross的客户服务部门查询更多信息, 电话号码为800-722-1471 (TTY: 800-842-5357)。