Introduction

Radiofrequency ablation is a way of destroying part of nerves to treat pain. An electrical current is produced by radio waves. The current is applied to a small area of nerve tissue, thus destroying (ablating) part of the nerve and interrupting pain signals. Pulsed radiofrequency is similar to radiofrequency ablation in that it is still being studied. Instead of a constant current being applied, pulsed radiofrequency calls for short bursts of energy. These intermittent bursts of energy allow more electrical current to be applied while keeping temperatures below the range that would ablate the nerve. Pulsed radiofrequency is investigational (unproven) to treat pain. More, larger, and longer studies are needed to see if this technique is safe and effective.

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>Pulsed radiofrequency</td>
<td><strong>Pulsed radiofrequency for the treatment of various chronic pain syndromes is considered investigational, including but not limited to the following:</strong></td>
</tr>
<tr>
<td></td>
<td>• Chronic facial and head pain (persistent idiopathic facial pain (PIFP)/sphenopalatine ganglion)</td>
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<tr>
<td></td>
<td>• Coccydynia</td>
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<td></td>
<td>• Complex regional pain syndrome (reflex sympathetic dystrophy)</td>
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<td></td>
<td>• Diabetic peripheral neuropathy</td>
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<td></td>
<td>• Discogenic pain</td>
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<td></td>
<td>• Facet joint pain (cervical, lumbar, thoracic, sacro-iliac)/zygapophyseal joint pain</td>
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<td></td>
<td>• Headaches (eg, cervicogenic, migraines, cluster, tension)</td>
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<tr>
<td></td>
<td>• Inguinal neuralgia</td>
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<td></td>
<td>• Intercostal neuralgia (post-surgical thoracic pain)</td>
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<td></td>
<td>• Low back pain</td>
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<td>• Lumbo-sacral radicular pain (eg, dorsal root ganglion)</td>
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<td></td>
<td>• Meralgia paresthetica (burning pain in the outer thigh related to lateral femoral cutaneous nerve entrapment)</td>
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<td>• Metacarpal or metatarsal joint pain of the hands and feet</td>
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<td></td>
<td>• Morton’s neuroma</td>
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<td></td>
<td>• Myofascial pain syndrome</td>
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<td>• Neck pain</td>
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<td>• Occipital neuralgia</td>
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<td>• Orchialgia (testicular pain/spermatic cord)</td>
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<td></td>
<td>• Osteoarthritis of the knee or hip</td>
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<td>• Pelvic pain (eg, superior hypogastric plexus treatment for interstitial cystitis)</td>
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<td></td>
<td>• Peripheral neuromas</td>
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<td></td>
<td>• Piriformis syndrome (buttock pain and/or pain in the back of the lower extremity related to sciatic nerve irritation)</td>
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<td></td>
<td>• Plantar fasciitis</td>
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<td>• Post herpetic neuralgia (ophthalmic neuralgia)</td>
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<td></td>
<td>• Pudendal neuralgia</td>
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<td>• Shoulder pain (suprascapular nerve)</td>
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<td>• Tarsal tunnel syndrome (compression neuropathy from entrapment of the posterior tibial nerve)</td>
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<tr>
<td>Procedure</td>
<td>Investigational</td>
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</tr>
<tr>
<td></td>
<td>• Trigeminal neuralgia</td>
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<tr>
<td></td>
<td>• Vulvodynia</td>
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</table>

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td></td>
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<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
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</tbody>
</table>

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### Related Information

N/A

### Evidence Review

#### Description

Pulsed radiofrequency (PRF) is a non- or minimally neurodestructive technique, where short bursts of radiofrequency energy are applied to nervous tissue to treat various chronic pain syndromes. It is seen as an alternative to continuous (non-pulsed) radiofrequency ablation, as it is theorized to have significantly less complications or side effects. Its exact mechanism of action is unclear.
Background

Pulsed radiofrequency was first used in 1996 as a less destructive alternative to continuous (non-pulsed) radiofrequency. Pulsed radiofrequency is delivered in short bursts, twice per second, followed by a quiet phase in which no current is applied. This allows for cooling of the electrode keeping it below the neurodestructive threshold of 45° C. Pulsing the radiofrequency current allows the power output of the generator to be greatly increased, allowing for far stronger electrical fields than in continuous radiofrequency. For example, the voltage output is usually 15-25 volts for the continuous mode radiofrequency. The pulsed radiofrequency output is 45 volts. As a result, higher voltages can be applied in pulsed radiofrequency. Because the average temperature near the pulsed radiofrequency electrode does not reach the neurodestructive range, the risk of destroying nearby tissue is reduced.

Pulsed radiofrequency has been used in the treatment of peripheral neuropathies, arthrogenic pain, painful trigger points, radiculopathy, and many other chronic pain syndromes. Unlike the known side effects of continuous radiofrequency such as, neuritis-like reactions, motor deficits, and the risk of deafferentation pain syndrome, pulsed radiofrequency seems to have few side effects and is seen as relatively safe. However, even though there is much anecdotal evidence which favors the use of pulsed radiofrequency for the use of pain relief without nervous tissue damage, especially in the treatment of neuropathic pain, there is a lack of randomized controlled trials (RCTs) substantiating its efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Summary of Evidence

For individuals with various chronic pain syndromes, especially neuropathic pain who received pulsed radiofrequency, the evidence includes a small number of RCTs, non-randomized controlled trials, prospective uncontrolled trials, retrospective studies, case series, and case reports. The majority of the uncontrolled and observational studies reported clinical efficacy of pulsed radiofrequency, however many of these studies had limitations. The controlled clinical data is limited and with inconsistent findings. Further research in the clinical and biological effects of pulsed radiofrequency is needed including well-designed, randomized controlled clinical trials with a large sample size and long-term follow-up to determine the therapeutic effect and safety of this treatment modality. There is also a lack of data comparing pulsed radiofrequency with conventional treatments. As such, it is unknown if pulsed radiofrequency offers any treatment advantage over other conventional treatments. 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 Clinical Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
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<tr>
<td>NCT03567590</td>
<td>The Efficacy and Safety of Sphenopalatine Ganglion Pulsed Radiofrequency Treatment for Cluster Headache</td>
<td>80</td>
<td>May 2021 recruiting</td>
</tr>
<tr>
<td>NCT02915120</td>
<td>Ultrasound-Guided Pulsed Radiofrequency in the Treatment of Patients with Osteoarthritis Knee</td>
<td>142</td>
<td>Dec 2018 recruiting</td>
</tr>
<tr>
<td>NCT03228316</td>
<td>Superior Hypogastric Plexus Block Versus Pulsed Radiofrequency for Chronic Pelvic Cancer Pain</td>
<td>40</td>
<td>Not yet recruiting, Estimated start date Oct 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians

The American Society of Interventional Pain Physicians (ASIPP) published an updated guideline on interventional techniques in the management of chronic spinal pain Part II guidance and recommendation which states the following:

- Lumbar spine
  - The evidence for therapeutic facet joint interventions is good for conventional radiofrequency, limited for pulsed radiofrequency, fair to good for lumbar facet joint nerve blocks, and limited for intraarticular injections
  - For sacroiliac interventions, the evidence for cooled radiofrequency neurotomy is fair; limited for intraarticular injections and periarticular injections; and limited for both pulsed radiofrequency and conventional radiofrequency neurotomy
- **Cervical Spine**
  - Evidence for therapeutic facet joint intervention is fair for conventional cervical radiofrequency neurotomy
- **Thoracic Spine**
  - Evidence is limited for radiofrequency neurotomy

### 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 generators and probes have been cleared for marketing through the U.S. Food and Drug Administration (FDA) 510(k) process.

### References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>09/01/18</td>
<td>New policy, approved August 14, 2018, effective December 6, 2018. Add to Surgery section. Policy created with a literature review through July 2018. Pulsed radiofrequency for the treatment of various chronic pain syndromes is considered investigational.</td>
</tr>
</tbody>
</table>
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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  - Qualified interpreters
  - Information written in other languages

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Email AppealsDepartmentInquiries@Premera.com

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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

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