PROVIDENCE HEALTH PLANS AND PROVIDENCE HEALTH ASSURANCE MEDICAL POLICY

Radiofrequency Lesioning or Cryosurgery/Cryotherapy as an Alternative to Surgical Treatment for Plantar Fasciitis

Effective Date: 7/1/2018

Technology Assessment Committee Approved Date: 1/08; 5/09
Medical Policy Committee Approved Date: 7/11; 5/13; 8/14; 9/15; 6/16; 8/17; 5/18

Medical Officer Date

See Policy CPT CODE section below for any prior authorization requirements

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) for coverage determinations.

For other lines of business, refer to the Policy Criteria section below:

POLICY CRITERIA

All Lines of Business Except Medicare

I. Radiofrequency lesioning or cryosurgery/cryotherapy as treatment of plantar fasciitis is considered investigational and is not covered.

Medicare Members

II. Radiofrequency lesioning or cryosurgery/cryotherapy as treatment of plantar fasciitis is considered not medically necessary and is not covered.

Link to Policy Summary

POLICY GUIDELINES

The codes 0441T and 64640 are not specific to the procedures and/or indications addressed in this
policy. Guidelines per line of business are as follows:

**All lines of Business except Medicare:** 64640 and 0041T will be considered investigational for the therapies addressed in this policy for the diagnosis of plantar fasciitis (M72.2).

**Medicare only:**
- 64640 will be considered investigational for the therapies addressed in this policy for the diagnosis of plantar fasciitis (M72.2).
- 0441T will be considered not medically necessary for plantar fasciitis per this policy. However, for all other indications requested with 0441T, please refer to the “Investigational and Non-Covered Medical Technologies (CMS Only)” medical policy in the Medical Policy Cross References section below.

**CPT CODES**

<table>
<thead>
<tr>
<th>All Lines of Business Except Medicare</th>
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<tr>
<td><strong>No PA Required</strong></td>
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<tr>
<td>0441T Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve</td>
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<td><strong>Not covered</strong></td>
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<tr>
<td><strong>No PA Required</strong></td>
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<td>64640 Destruction by neurolytic agent; other peripheral nerve or branch</td>
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<th>Unlisted Codes</th>
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<td>All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as Not Covered.</td>
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<td>20999 Unlisted procedure, musculoskeletal system, general</td>
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<td>28899 Unlisted procedure, foot or toes</td>
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<td>64999 Unlisted procedure, nervous system</td>
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DESCRIPTION

Plantar Fasciitis

Plantar fasciitis is a condition in which the connective tissue between the heel bone and base of the toes, called the plantar fascia, becomes inflamed. Plantar fasciitis is often localized to the plantar medial aspect of the heel, and is the most common cause of heel pain. The pain is typically worse in the morning but improves with movement. Diagnosis of plantar fasciitis is typically made through clinical history and physical examination.¹

“Plantar fasciitis is primarily treated nonoperatively, and up to 95% of patients have symptom resolution within 12 to 18 months. Conservative treatments for plantar fasciitis include modification of activities (e.g., avoidance of repetitive impact activities), plantar fascia stretching and ice massage, taping, night splints, orthotics, analgesia, anti-inflammatory agents, and local steroid injections. Surgical interventions, such as partial or complete fasciotomy, are reserved for the most recalcitrant cases and are rarely used.”¹ Currently, there are several minimally invasive treatments being explored as alternatives to conservative and surgical management of plantar fasciitis. This policy will address the following minimally invasive therapies: radiofrequency lesioning and cryosurgery (also known as cryotherapy)

Radiofrequency Lesioning

Radiofrequency lesioning, also known as radiofrequency ablation (RFA), radiofrequency nerve ablation (RFNA), radiofrequency neurotomy, denervation, or rhizotomy, is a minimally invasive treatment proposed to temporarily reduce pain caused by plantar fasciitis. During the procedure, a radiofrequency cannula and probe are inserted into the heel. The probe is heated to 80-90 degrees celsius and heat is applied to the target nerve for 1-3 minutes. The proposed mechanism of action is that radiofrequency energy causes thermal damage to the nerve, which reduces or eliminates the perception of pain. The procedure is typically performed under local anesthetic or light sedation as an outpatient procedure. It may be performed with fluoroscopic or ultrasonographic guidance to facilitate localization of the target nerves. Recovery time is estimated to be between 1-4 weeks, and effects are said to last up to 24 months.¹

Cryosurgery

Cryosurgery, also referred to as cryoablation, cryotherapy, cryodenervation or cryogenic neuroablation, has also been proposed as minimally invasive treatment for individuals with plantar fasciitis. This technique involves the use of a specialized probe called a cryoprobe and administration of intense cooling applications to the target nerve, usually on the proximal plantar area of the foot. The proposed mechanism of action is that freezing destroys nerve tissue by causing extensive vascular damage to the endoneural capillaries or blood vessels supplying the nerves, thereby interrupting the transmission of pain impulses. Treatment effects have been reported two last up to 24 months.
REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of radiofrequency lesioning and cryosurgery as potential treatments for plantar fasciitis. Below is a summary of the available evidence identified through March of 2018.

Because of the variable natural history of plantar fasciitis and the subjective nature of outcome measures like pain, randomized clinical trials (RCTs) are needed to determine whether outcomes are truly improved with the use of radiofrequency lesioning or cryosurgery as opposed to placebo effect. Ideally, trials should be sufficiently powered to avoid spurious results, include homogenous patient populations, longer follow up periods, and report objective outcome measures such as imaging in addition to standardized methods of measuring subjective outcomes like pain severity and functional impairment.

Radiofrequency Lesioning

In 2017, Hayes published a review on the safety and effective of radiofrequency lesioning compared to convention treatments for recalcitrant plantar fasciitis in adults, including five studies. Only two of the studies were comparative and the remaining three studies were small case series. The comparative studies included a randomized crossover trial that compared radiofrequency lesioning with sham treatment (n=17 patients) and a nonrandomized controlled trial that compared radiofrequency lesioning with pulsed radiofrequency. Hayes reported a rating of “D2” for the use of radiofrequency lesioning in adults with recalcitrant plantar fasciitis. The review stated that the body of evidence is of “fair to very poor quality and limited by small sample sizes, lack of comparison groups, and other methodological flaws. Substantial uncertainty remains regarding the durability of the treatment effect, the comparative efficacy of [radiofrequency lesioning] compared with other minimally invasive treatments, patient selection, and safety.”

Of note, there were several other nonrandomized studies published prior to the Hayes review that were not included in the review due to poor quality as a result of methodologic limitations. These excluded studies suffered from a lack of reporting of statistical values and reported different outcomes measures, making conclusions drawn about treatment efficacy difficult to determine.

No additional studies evaluating the safety or efficacy of radiofrequency lesioning to treat plantar fasciitis were identified after the publication of the Hayes review.

Cryotherapy/ Cryosurgery

There are a limited number of studies comparing cryosurgery to standard of care treatments for plantar fasciitis. Evidence consists of small case series and one small randomized controlled trial (RCT). All studies suffer from limitations including small sample size and evaluation of subjective pain alone (e.g., patient reported pain, as measured by the visual analog scale [VAS]) without measurement of objective data (e.g., imaging studies). Further RCTs are needed to determine the efficacy of cryosurgery as a
Radiofrequency Lesioning or Cryosurgery/Cryotherapy as an Alternative to Surgical Treatment for Plantar Fasciitis

treatment option for plantar fasciitis, and should include larger sample sizes, longer follow periods and double-blinding to establish the overall effectiveness of this procedure and include comparative studies against other treatments.

CLINICAL PRACTICE GUIDELINES

No clinical practice guidelines were identified that recommended the use of either radiofrequency lesioning or cryosurgery as treatment for plantar fasciitis.

CENTERS FOR MEDICARE & MEDICAID

As of 4/2/2018, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses radiofrequency lesioning or cryosurgery for specifically for plantar fasciitis.

Cryoablation of the lower extremity distal/peripheral nerves (code 0441T), which is addressed in this policy, is not specific to plantar fasciitis. This code was identified in the Local Coverage Determination (LCD) L35008: Non-Covered Services\textsuperscript{10}, where it is considered not medically necessary for all indications. Please refer to the “Investigational and Non-Covered Medical Technologies (CMS Only)” medical policy in the Medical Policy Cross References section below if 0441T is billed for indications other than plantar fasciitis.

POLICY SUMMARY

There are a limited number of studies comparing radiofrequency lesioning or cryosurgery to standard of care treatments for plantar fasciitis, such as nonoperative treatments or surgical repair. The body of evidence evaluating the efficacy of radiofrequency lesioning and cryosurgery or cryotherapy to treat plantar fasciitis is limited by a lack of randomized controlled trials. In addition, published nonrandomized comparative studies and case series are of small sample size, retrospective study design and of poor quality. Further good quality prospective comparative studies are needed to evaluate the clinical utility of radiofrequency lesioning and cryosurgery as alternative treatments of plantar fasciitis.

INSTRUCTIONS FOR USE

Providence Health Plan (PHP) and Providence Health Assurance (PHA) Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. PHP and PHA Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. PHP and PHA reserve the right to determine the application of Medical Policies and make revisions to its Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.
The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHP and PHA Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

MEDICAL POLICY CROSS REFERENCES

Investigational and Non-Covered Medical Technologies (CMS Only), MED393

REFERENCES

1. Hayes. Health Technology Brief. Radiofrequency Nerve Ablation for Treatment of Plantar Fasciitis. Published 12/14/2017. [https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=78086&searchStore%24search_type%3Dpharse%24icd%3D%24keywords%3Dradiofrequency%24lesioning%24status%3Dall%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%3Dâ€œsearchRelevance]. Accessed 04/02/2018.


