

MEDICAL POLICY	Radiofrequency Ablation or Cryoablation for Plantar Fasciitis
Effective Date: 5/1/2021	Medical Policy Number: 284
 5/1/2021	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; 2/19; 2/2020; 8/2020; 2/2021
Medical Officer	Date

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

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) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

I. Radiofrequency ablation and cryoablation as treatments of plantar fasciitis are considered **investigational and are not covered.**

Link to [Policy Summary](#)

BILLING GUIDELINES

- The codes 0441T and 64640 are not specific to the procedures and/or indications addressed in this policy.
- 64640 and 0441T will be considered investigational for the therapies addressed in this policy for the diagnosis of plantar fasciitis (M72.2) or related ICD codes:

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G57.60 – G57.63.	M4728	M5388
G5700 – G5703	M47818	M5414 – M5417
M25751 – M25759	M47898	M5430 – M545
M4308	M4808	M7060 – M7072
M4318	M488X8	M729
M4328	M5117	M7600 – M7622
M461	M532X8	
M4698	M533	

CPT CODES

All Lines of Business	
No Prior Authorization Required	
Note: The following codes are investigational and not covered when billed with the diagnosis of plantar fasciitis (M72.2) or related ICD codes (see Billing Guidelines above).	
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve
64640	Destruction by neurolytic agent; other peripheral nerve or branch
Unlisted Codes	
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 .	
20999	Unlisted procedure, musculoskeletal system, general
28899	Unlisted procedure, foot or toes
64999	Unlisted procedure, nervous system

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 ablation and cryoablation.

Radiofrequency Ablation

Radiofrequency ablation (RFA), also known as radiofrequency (RF) lesioning, RF nerve ablation (RFNA), RF 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

Cryoablation

Cryoablation, also referred to as cryosurgery, 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 to 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 ablation (RFA) and cryoablation as potential treatments for plantar fasciitis. Below is a summary of the available evidence identified through December 2020.

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 RFA or cryoablation 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 Ablation

In 2017 (reviewed in 2020), Hayes published a review on the safety and effective of radiofrequency ablation (RFA) compared to convention treatments for recalcitrant plantar fasciitis in adults, including five studies.¹ 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 RFA with sham treatment (n=17 patients) and a nonrandomized controlled trial that compared RFA with pulsed radiofrequency. Hayes reported a **rating of “D2”** for the use of RFA 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 [RFA] 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.²⁻⁶

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

Cryoablation

There are a limited number of studies comparing cryoablation to standard of care treatments for plantar fasciitis. Evidence consists of small case series and one small randomized controlled trial (RCT).⁷⁻¹⁰ 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 cryoablation as a 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

American College of Foot and Ankle Surgeons (ACFAS)

In 2018, the ACFAS published a non-evidence based consensus statement of the diagnosis and treatment of adult acquired infracalcaneal heel pain.¹¹ The panel concluded that the safety and efficacy regarding both cryosurgery and radiofrequency ablation were “uncertain – neither appropriate nor inappropriate.”¹¹ Authors called for additional, long-term research assessing these treatments efficacy.

CENTERS FOR MEDICARE & MEDICAID SERVICES

As of 12/29/2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses radiofrequency ablation or cryoablation for the treatment of plantar fasciitis.

POLICY SUMMARY

There are a limited number of studies comparing RFA or cryoablation to standard of care treatments for plantar fasciitis, such as nonoperative treatments or surgical repair. The body of evidence evaluating the efficacy of RFA and cryoablation 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 RFA and cryoablation as alternative treatments of plantar fasciitis.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company 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. The Companies reserve the right to determine the application of Medical Policies and make revisions to 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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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