Radiofrequency Ablation or Cryoablation for Plantar Fasciitis

MEDICAL POLICY NUMBER: 165

Effective Date: 12/1/2023

Last Review Date: 9/2023

Next Annual Review: 9/2024

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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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 Company Medical Policy will be resolved in favor of the coverage agreement. 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.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP 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.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Radiofrequency ablation and cryoablation as treatments of plantar fasciitis are considered **not medically necessary**.

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

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 two last up to 24 months.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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 August 2023.

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 2020 (archived in 2021), 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

<u>American College of Foot and Ankle Surgeons (ACFAS)</u>

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.

EVIDENCE 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.

BILLING GUIDELINES AND CODING

CODES*		
CPT	0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve
	20999	Unlisted procedure, musculoskeletal system, general
	28899	Unlisted procedure, foot or toes
	64640	Destruction by neurolytic agent; other peripheral nerve or branch
	64999	Unlisted procedure, nervous system

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
12/2023	Annual update. Changed denial from investigational to not medically necessary.