

Subject: Cryoablation for Plantar Fasciitis and Plantar Fibroma
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Description/Scope

This document addresses the use of cryoablation, also referred to as cryosurgery or cryogenic neuroablation, for the treatment of plantar fasciitis and plantar fibroma.

Note: Please see the following related documents for additional information:

- [CG-SURG-25 Injection Treatment for Morton's Neuroma](#)
- [SURG.00045 Extracorporeal Shock Wave Therapy](#)
- [SURG.00088 Coblation® Therapies for Musculoskeletal Conditions](#)

Position Statement

Investigational and Not Medically Necessary:

Use of cryoablation (for example, cryosurgery, neuroablation) for the treatment of either plantar fasciitis or plantar fibroma is considered **investigational and not medically necessary**.

Rationale

Plantar Fasciitis and Plantar Fibroma

One randomized controlled trial (RCT) compared cryotherapy to a different treatment for plantar fasciitis. In 2020, Catal and colleagues published findings of a single center RCT conducted in Turkey comparing cryotherapy and surgery (endoscopic plantar fasciitis release [EPFR]) in 48 individuals with plantar fasciitis resistant to 6 months of conservative treatment. The primary outcome was the American Orthopedic Foot and Ankle Society ankle/hindfoot scale (AOFAS-AHS) measurement. This has a potential range of 0-100 points, with a higher score indicating better outcomes. At baseline, mean scores were 51.0 in the EPFR group and 53.9 in the cryosurgery group ($p=0.39$). At 6 months, mean scores were significantly higher in the EPFR group than the cryosurgery group (82.4 versus 71.7, $p=0.007$) and there was not a significant between-group difference at 1 year ($p=0.11$). No complications were reported in the EPFR group. This study did not clearly demonstrate a benefit from cryotherapy; RCTs are needed that compare cryotherapy with sham treatment or commonly used alternatives such as medication, physical therapy and/or splints.

A systematic review of RCTs on surgical interventions for plantar fasciopathy, which searched the literature through February, 2022, identified the Catal (2020) study (discussed above), but no additional RCTs on cryotherapy (MacRae, 2022).

Allen and colleagues (2007) published data on 59 individuals (61 heels) who had failed conservative therapy and were considered surgical candidates. The primary outcome was pain using an 11-point visual analog scale (VAS) that was assessed preoperatively and up to 1 year of follow-up. The mean pain rating was 8.38 before cryosurgery (day 0) compared with a mean pain rating of 1.26 after a year, a statistically significant improvement after surgery $p<0.0001$. This study lacks a control group with which to compare pain outcomes.

Cavazos and colleagues (2009) published findings of a retrospective case series in individuals with recalcitrant heel pain who had failed 6 months of conservative care. Pain was measured using a Numeric Pain Scale (NPS, 0 to 10) at 3 weeks and 24 months. A total of 106 individuals had successful pain relief and 31 individuals failed to gain relief; the success and failure rates were 77.4% and 22.6%, respectively. Mean pain before cryosurgery was 7.6, after cryosurgery at 3 weeks was 1.6 ($p<0.0005$), and after cryosurgery at 24 months was 1.1 ($p<0.0005$). Limitations of the analysis were the multiple etiologies of the subjects' heel pain and the variable treatment techniques of the clinicians performing the procedure.

One small retrospective series (Ahmed, 2018) evaluated cryoablation for symptomatic plantar fibromas. The study included 4 individuals with 5 plantar fibromas. Mean pain score (on a 10-point scale) was 5.8 at baseline and decreased to 0.4 after treatment. The study was limited by a small number of participants, lack of blinding and lack of a comparison group.

There continues to be insufficient scientific evidence published in peer-reviewed medical journals that permits reasonable conclusions concerning the effect of cryoablation on health outcomes. There is a lack of published studies comparing cryoablation to sham or alternative treatments for plantar fasciitis or plantar fibroma.

Background/Overview

The plantar fascia is a ligament-like structure that covers the bottom of the foot, extending from the heel bone to the base of the toes, which protects the bottom of the heel bone and acts like a shock absorber for the bottom of the foot. In many individuals, the plantar fascia may become irritated, causing a condition called plantar fasciitis. This is a common cause of heel pain. The cause of this condition is not entirely clear, but is associated with or due to repetitive trauma. It is common in several sub-groups of people, including runners and other athletes, people who have jobs that require a fair amount of walking or standing (especially if it is done on a hard surface), and in some cases it is seen in people who have put on weight, including through pregnancy. Most people who have plantar fasciitis recover with conservative treatments in just a few months with use of pain relievers (such as ibuprofen or naproxen to ease pain and inflammation), physical therapy (stretching and strengthening exercises), night splints, and over-the-counter orthotics (such as, heel cups, cushions, or custom-fitted arch supports).

Plantar fibromas are relatively uncommon, benign but locally invasive lesions that are characterized by fibrous proliferation arising from the plantar fascia. On clinical examination, fibrous nodules in the plantar arch with frequent bilateral involvement characterize plantar fibroma. Typically, these nodules are painless or cause only vague or perhaps moderate pain. Fascial scarring and contracture may be seen late in the disease course. Radiographic findings are usually normal. Diagnosis is made with palpation of plantar nodules. Treatment is initially conservative, but surgery may be indicated in individuals with painful or deep infiltrating lesions. The

high incidence of recurrence after surgical excision and the potential for problematic wound healing and scarring presents a significant challenge in the management of this condition.

Cryoablation, also referred to as cryosurgery or cryogenic neuroablation, has been proposed as an alternative treatment for individuals who have failed prior attempts of conservative therapies for plantar fasciitis and plantar fibroma. Cryoablation is a minimally invasive outpatient procedure typically performed on the proximal plantar area of the foot. After administration of a local anesthetic, a small incision is made adjacent to the area of primary discomfort. A specialized probe is inserted into the area of "trigger point" type pain and the area is then treated with a series of cooling then thawing cold applications. The resultant 6 to 8 mm "ice ball" formed at the cryoprobe tip will destroy nerve tissue by causing extensive vascular damage to the endoneural capillaries or blood vessels supplying the nerves. Freezing the particular areas of pain caused by plantar fasciitis creates a block that stops the conduction of pain. No sutures are necessary and a small dressing is applied to the surgical area. There is minimal need for post-operative pain medication and most individuals promptly resume normal activities.

A cryosurgery device is described in the U.S. Food and Drug Administration (FDA) database as a "device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site" (FDA, 2023). There are numerous cryosurgery devices with 510(k) clearance, although none of these devices is approved specifically for the indications of plantar fasciitis or plantar fibroma. Devices with FDA clearance include, but are not limited to, the Cryo-PaC™ and CryoStar™ Systems (CryoMedical Instruments, Ltd., Mansfield, Nottinghamshire, England, UK) and the Cryo-Touch series of devices (MyoScience, Inc., Redwood City, CA).

Potential Complications

There have been few complications reported with cryoablation procedures for plantar fasciitis and plantar fibroma. Infection has rarely been reported; the most common post-procedure symptom described is the development of pain in another location of the heel or arch. This pain usually responds to the use of nonsteroidal anti-inflammatory drugs (NSAIDs) or over-the-counter arch supports.

Definitions

Cryoablation: A minimally invasive procedure using a closed-probe, gas-based system. This procedure uses extremely cold temperatures to selectively destroy nerve endings to create a block that stops the conduction of pain.

Plantar fasciitis: Inflammation of thick tissue on the bottom of the foot caused by chronic irritation resulting in pain while standing, walking, and running.

Plantar fibroma: A single mass or clusters of fibrous, nodular lesions that form within a ligament in the arch of the foot.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

For the following codes **when specified as cryoablation or cryosurgery for plantar fasciitis or fibroma:**

CPT

28899	Unlisted procedure, foot or toes [when specified as cryoablation of plantar fasciitis or plantar fibroma]
64640	Destruction by neurolytic agent (eg, chemical, thermal, electrical or radiofrequency); other peripheral nerve or branch [when specified as cryosurgery]

ICD-10 Procedure

015G0ZZ	Destruction of tibial nerve, open approach
015G3ZZ	Destruction of tibial nerve, percutaneous approach
015G4ZZ	Destruction of tibial nerve, percutaneous endoscopic approach

ICD-10 Diagnosis

M72.2	Plantar fascial fibromatosis (plantar fasciitis)
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References

Peer Reviewed Publications:

1. Ahmed M, Weinstein JL, Hussain J, et al. Percutaneous ultrasound-guided cryoablation for symptomatic plantar fibromas. *Cardiovasc Intervent Radiol*. 2018; 41(2):298-304.
2. Allen BH, Fallat LM, Schwartz SM. Cryosurgery: an innovative technique for the treatment of plantar fasciitis. *J Foot Ankle Surg*. 2007; 46(2):75-79.
3. Çatal B, Bilge A, Ulusoy RG. Endoscopic plantar fascia release versus cryosurgery for the treatment of chronic plantar fasciitis: A prospective randomized study. *J Am Podiatr Med Assoc*. 2020; 110(5):Article_3.
4. Cavazos GJ, Khan KH, D'Antoni AV, et al. Cryosurgery for the treatment of heel pain. *Foot Ankle Int*. 2009; 30(6):500-505.
5. Costantino C, Vulpiani MC, Romiti D, et al. Cryoultrasound therapy in the treatment of chronic plantar fasciitis with heel spurs. A randomized controlled clinical study. *Eur J Phys Rehabil Med*. 2014; 50(1):39-47.
6. MacRae CS, Roche AJ, Sinnott TJ et al. What is the evidence for efficacy, effectiveness and safety of surgical interventions for plantar fasciopathy? A systematic review. *PLoS One*. 2022; 17(5):e0268512.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Thomas JL, Christensen JC, Kravitz SR, et al. American College of Foot and Ankle Surgeons (ACFAS). The diagnosis and treatment of heel pain: a clinical practice guideline - revision 2010. *J Foot Ankle Surg*. 2010; 49:S1-S19.
2. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Cryogenic surgical device. August 31, 2023. Available at: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-882/subpart-E/section-882.4250>.

Websites for Additional Information

1. American Academy of Orthopaedic Surgeons (AAOS). Choosing Wisely: Treating Plantar Fasciitis. OrthoInfo. Plantar fasciitis and bone spurs. Available at: <https://www.choosingwisely.org/patient-resources/treating-plantar-fasciitis/>. Accessed on September 14, 2023.

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Cryogenic Neuroablation
Cryosurgery

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Background/Overview and References sections updated.
Reviewed	11/10/2022	MPTAC review. Rationale and References sections updated.
Reviewed	11/11/2021	MPTAC review. References section updated.
Reviewed	11/05/2020	MPTAC review. Background/Overview and References sections updated.
Reviewed	11/07/2019	MPTAC review. Background/Overview and References sections updated.
Reviewed	01/24/2019	MPTAC review. Rationale and References sections updated.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale, Background/Overview, References, and Websites for Additional Information sections.
Reviewed	05/04/2017	MPTAC review. Updated Description, Rationale, Background/Overview, Definitions, References, Websites for Additional Information, and Index sections.
Reviewed	05/05/2016	MPTAC review. Updated Background, References, and Websites for Additional Information sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated Rationale, Background, and References sections.
Reviewed	05/15/2014	MPTAC review. Minor format change to Position Statement. Updated Rationale, Definitions, References, Websites for Additional Information, and Index sections.
Reviewed	05/09/2013	MPTAC review. Updated Rationale, References, Websites for Additional Information, and Index.
Reviewed	05/10/2012	MPTAC review. Updated Background, References, and Websites for Additional Information.
Reviewed	05/19/2011	MPTAC review. Updated Background, Definitions, References, and Websites for Additional Information.
Reviewed	05/13/2010	MPTAC review. Updated Rationale and References.
Reviewed	05/21/2009	MPTAC review. Clarified Position Statement. Updated Rationale, Background, Definitions, and References.
Reviewed	05/15/2008	MPTAC review. Updated References.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
New	05/17/2007	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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