



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 07/05/11
LAST REVIEW DATE: 05/27/14
LAST CRITERIA REVISION DATE: 05/27/14
ARCHIVE DATE:

FOOT DISORDER TREATMENTS

- Coblation®
- Collagen Implant
- Cryosurgery
- Extracorporeal Shock Wave Therapy (ESWT)
- Neuroablation

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Methods for treating foot disorders.

Coblation:

A process that uses radiofrequency energy to create plasma by way of a conductive medium such as saline solution. The plasma's energized particles break the molecular bond within tissue causing the tissue to dissolve at low temperatures resulting in volumetric removal of target tissue. Coblation is sometimes referred to as cold or controlled ablation and has been investigated as a treatment for Achilles tendinitis/tendinosis, musculoskeletal tendinitis/tendinosis, plantar fasciitis and plantar fasciosis. The terms TOPAZ® and TOPAZ® microdebridement may also be used for coblation.

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FOOT DISORDER TREATMENTS (cont.)

Description: (cont.)

Collagen Implant:

Collagen is a fibrous protein found in the skin, bone, ligaments and cartilage. The most common type of synthetic collagen is bovine collagen. Collagen can be injected for the purpose of soft tissue augmentation in the treatment of painful foot disorders, e.g., keratotic lesions, hammer toe and bone spurs.

Keratotic Lesions:

Dense thickening of the keratin layer of the skin, primarily occurring on the sole of the foot. Keratotic lesions include corns and calluses.

Cryosurgery:

Cryosurgery is a minimally invasive procedure that has been investigated for the treatment of various foot disorders. A specialized probe is inserted into the affected area and extreme cold is applied to freeze nerve tissue and block pain conduction. Cryosurgery is also known as cryoablation, cryotherapy or cryoneurolysis.

Extracorporeal shock wave therapy (ESWT):

ESWT, also known as orthotripsy, is a noninvasive procedure that has been investigated for the treatment of pain. It is the process of applying low or high energy intensity shock or sound waves to a targeted site for the treatment of musculoskeletal conditions including plantar fasciitis, lateral epicondylitis (tennis elbow), and shoulder tendinitis/calcifications. ESWT for musculoskeletal conditions is usually an outpatient procedure. The Ossatron and Epos Ultra devices require the use of general anesthesia. The Minilith® SL1 and OrthoWave® have not received FDA approval.

Neuroablation:

A procedure designed to destroy neural tissue for the treatment of chronic pain. A lesion is created on the nerve to interrupt the nerve impulse/pathway thus preventing the pain signal from traveling to the brain. Neuroablation methods addressed in this guideline are:

Chemical:

Administration of phenol or alcohol around the nerve.

Radiofrequency:

Application of heat to the nerve.

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FOOT DISORDER TREATMENTS (cont.)

Criteria:

Coblation

- Coblation for the treatment of foot disorders is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.
- These foot disorders include, *but are not limited to*:
 - Achilles tendinitis/tendinosis
 - Foot tendinitis/tendinosis
 - Plantar fasciitis
 - Plantar fasciosis

Collagen Implant:

COVERAGE FOR FOOT CARE, INCLUDING TRIMMING OF NAILS OR TREATMENT OF CORNS AND CALLUSES, EXCEPT WHEN MEDICALLY APPROPRIATE FOR DIABETES, NEUROLOGICAL INVOLVEMENT OR PERIPHERAL VASCULAR DISEASE OF THE FOOT OR LOWER LEG IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.

- **If benefit coverage for foot care is available**, collagen implant for the treatment of keratotic lesions of the foot (e.g., corns and calluses) is considered ***medically necessary*** for individuals with **ANY** of the following conditions:
 1. Diabetes
 2. Neurological involvement of the feet or lower legs
 3. Peripheral vascular disease of the feet or lower legs
- Collagen implant for treatment of keratotic lesions for all other conditions not previously listed or if above criteria not met, is considered foot care and a ***benefit plan exclusion***.

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FOOT DISORDER TREATMENTS (cont.)

Criteria: (cont.)

Collagen Implant: (cont.)

- Collagen implant as a surgical alternative for the treatment of **ANY** of the following is considered **medically necessary**:
 1. Bone spur
 2. Hammer toe
 3. To replace the soft tissue of the foot that functions to cushion the head of a metatarsal
- Collagen skin testing prior to a covered bovine collagen implant is considered **medically necessary**.
- Collagen implant for all other indications not previously listed or if above criteria not met is considered **cosmetic** and a **benefit plan exclusion**.

Cryosurgery:

- Initial cryosurgery, cryoablation, cryotherapy and cryoneurolysis for the treatment of a foot neuroma are considered **medically necessary**.
- Repeat cryosurgery, cryoablation, cryotherapy and cryoneurolysis for the treatment of a foot neuroma are considered **medically necessary** when a minimum of six months has elapsed since the previous successful treatment.
- Cryosurgery, cryoablation, cryotherapy and cryoneurolysis for the treatment of all other foot disorders or if above criteria not met are considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Other foot disorders include, *but are not limited to*:

- Plantar fasciitis
- Plantar fibroma
- Tarsal tunnel syndrome

FOOT DISORDER TREATMENTS (cont.)

Criteria: (cont.)

Extracorporeal Shock Wave Therapy (ESWT):

- Extracorporeal shock wave therapy for treatment of plantar fasciitis considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Neuroablation:

- Initial neuroablation of a neuroma of the foot by chemical or radiofrequency method is considered **medically necessary**.
- Repeat neuroablation of a neuroma of the foot by chemical or radiofrequency method is considered **medically necessary** when a minimum of six months has elapsed since the previous successful treatment.

Resources:

1. 2.01.40 BCBS Association Medical Policy Reference Manual. Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions. Re-issue date 02/13/2014, issue date 05/31/2001.
2. Allen BH, Fallat LM, Schwartz SM. Cryosurgery: an innovative technique for the treatment of plantar fasciitis. *J Foot Ankle Surg.* 2007 Mar-Apr 2007;46(2):75-79.
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4. American Medical Association. *Current Procedural Terminology (CPT ®)*.



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FOOT DISORDER TREATMENTS (cont.)

Resources: (cont.)

5. American Podiatric Medical Association. Freezing Temperatures Becoming Popular Method for Treating Chronic Pain. Accessed 06/25/08.
6. ArthroCare® Corporation. Topaz Info Fascia. Accessed 06/18/2010.
7. BCBS Association Technology Assessment Program. Extracorporeal Shock Wave Treatment for Chronic Plantar Fasciitis. 03/2005;19(18).
8. BlueCross BlueShield of AZ. *Benefit Plan Booklet*.
9. Buchbinder R, Ptasznik R, Gordon J, Buchanan J, Prabaharan V, Forbes A. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: a randomized controlled trial. *JAMA*. 2002 Sep 18 2002;288(11):1364-1372.
10. California Technology Assessment Forum. Extracorporeal Shock Wave Therapy for Plantar Fasciitis. *Blue Shield of California Foundation*. 02/13/2002.
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14. Fallat L. Chronic Plantar Fasciitis: Is Cryosurgery the Answer? *Podiatry Today*. 05/2005.

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Resources: (cont.)

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16. Goldstein SH. Cryosurgery for the Treatment of Tarsal Tunnel Syndrome. *Podiatry Management*. Oct 2006.
17. Healey K, Chen K. Plantar fasciitis: current diagnostic modalities and treatments. *Clin Podiatr Med Surg*. Jul 2010;27(3):369-380.
18. Karagounis P, Tsironi M, Prionas G, Tsiganos G, Baltopoulos P. Treatment of plantar fasciitis in recreational athletes: two different therapeutic protocols. *Foot Ankle Spec*. Aug 2011;4(4):226-234.
19. Lambarski D, Wendelken ME. A New Approach To Treating Painful Diabetic Neuropathy. *Podiatry Today*. Jan 2007.
20. Liu YJ, Wang ZG, Li ZL, et al. [Arthroscopically assisted radiofrequency probe to treat achilles tendinitis]. *Zhonghua Wai Ke Za Zhi*. 2008 Jan 15 2008;46(2):101-103.
21. Practice Management Information Corporation. *Health Care Procedure Coding System (HCPCS)*. 2005.
22. Practice Management Information Corporation. *International Classification of Diseases (ICD-9-CM)*. 2005.
23. Sean NY, Singh I, Wai CK. Radiofrequency microtenotomy for the treatment of plantar fasciitis shows good early results. *Foot Ankle Surg*. Dec 2010;16(4):174-177.
24. Shibuya N, Thorud JC, Humphers JM, Devall JM, Jupiter DC. Is percutaneous radiofrequency coblation for treatment of achilles tendinosis safe and effective? *J Foot Ankle Surg*. Nov-Dec 2012;51(6):767-771.
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26. Tay KS, Ng YC, Singh IR, Chong KW. Open technique is more effective than percutaneous technique for TOPAZ radiofrequency coblation for plantar fasciitis. *Foot Ankle Surg*. Dec 2012;18(4):287-292.
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Resources: (cont.)

28. Weil LJ, Glover JP, Weil LSS. A new minimally invasive technique for treating plantar fasciitis using bipolar radiofrequency: a prospective analysis. *Foot Ankle Spec.* 2008 Feb 2008;1(1):13-18.

FDA Premarket Approval Database for Orbasone®:

- FDA-approved indication: Chronic proximal plantar fasciitis in patients 18 years of age or older that have failed to respond to conservative therapy for six months or more.

FDA Premarket Approval Database for Orthospec™:

- FDA-approved indication: Proximal plantar fasciitis with or without heel spur in patients 18 years of age or older with symptoms of proximal plantar fasciitis that has failed to respond to conservative treatment for 6 months or more.

FDA Premarket Approval Database for Ossatron®:

- FDA-approved indication: Chronic proximal plantar fasciitis or chronic lateral epicondylitis that has failed to respond to conservative treatment for 6 months or more.

FDA Premarket Approval Database for Epos™ Ultra:

- FDA-approved indication: Chronic proximal plantar fasciitis that has failed to respond to conservative treatment for 6 months or more.

FDA Premarket Approval Database for EMS Swiss Dolorclast®:

- FDA-approved indication: Chronic proximal plantar fasciitis for patients 18 years of age or older with symptoms for 6 months or more and a history of unsuccessful conservative therapy. Chronic proximal plantar fasciitis is defined as heel pain in the area of the insertion of the plantar fascia on the medial calcaneal tuberosity.

FDA Premarket Approval Database for Zyderm CI®:

- FDA-approved indication: Implant, collagen for non-aesthetic use.



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FDA 510K Summary Statements for cryoanalgesia systems. Device names include, *but are not limited to:*

CryoStar™ Cryoanalgesia System
Cryo-PaC™ systems

- FDA-approved indication: For use in blocking pain by temporarily ablating the peripheral nerves.

FDA 510K Summary for ArthroCare® Topaz™ ArthroWands®:

- FDA-approved indication For debridement, resection, ablation and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Procedures	Body Structure as Described Below
- Fasciotomy	Foot
- Synovectomy	Foot
- Tendonotomy	Knee, Wrist, Elbow, Ankle, Shoulder, Foot
- Rotator Cuff Tendonotomy	Shoulder
- Capsulotomy	Foot