



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 05/27/15
LAST REVIEW DATE: 07/13/18
LAST CRITERIA REVISION DATE: 10/16/18
ARCHIVE DATE:

FOOT DISORDER TREATMENTS

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

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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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FOOT DISORDER TREATMENTS (cont.)

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.

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.

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. FDA approved devices include Ossatron®, Epos™, Sonocur® Basic, Orthospec™, Orbasone™ and Duolith® SD1. Ossatron and Epos require the use of general anesthesia. The Minilith® SL1 and OrthoWave® have not received FDA approval.

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.

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

FOOT DISORDER TREATMENTS (cont.)

Criteria: (cont.)

Collagen Implant: (cont.)

- 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**.
- 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:

For cryodenervation, cryoneurolysis and cryoablation for chronic pain unrelated to foot disorders, see BCBSAZ Medical Coverage Guideline #O261, “**Neuroablation and other Procedures for Treatment of Chronic Pain**”.

- Cryosurgery, cryoablation, cryotherapy and cryoneurolysis for the treatment of all foot disorders 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.



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Criteria: (cont.)

Extracorporeal Shock Wave Therapy (ESWT):

For ESWT for treatment of Peyronie's Disease, see BCBSAZ Medical Coverage Guideline #O722, "Peyronie's Disease Treatments".

- 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:

For radiofrequency of plantar fasciitis or knee osteoarthritis, see BCBSAZ Medical Coverage Guideline #O983, "Ablation of Peripheral Nerves to Treat Pain".

For radiofrequency neuroablation for treatment of chronic pain other than plantar fasciitis or knee osteoarthritis, see BCBSAZ Medical Coverage Guideline #O261, "Neuroablation and Other Procedures for Treatment of Chronic Pain".

- Neuroablation of a neuroma of the foot by radiofrequency 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.

- Alcohol injections for the treatment of Morton's neuroma 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, and
 4. Insufficient evidence to support improvement outside the investigational setting.



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Resources:

Literature reviewed 07/13/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 2.01.40 BCBS Association Medical Policy Reference Manual. Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions. Re-issue date 06/14/2018, issue date 05/31/2001.
2. 2.01.97 BCBS Association Medical Policy Reference Manual. Alcohol Injections for Treatment of Peripheral Neuromas. Re-issue date 06/14/2018, issue date 06/16/2016.
3. 7.01.147 BCBS Association Medical Policy Reference Manual. Ablation Procedures for Peripheral Neuromas. Re-issue date 06/14/2018, issue date 12/11/2014.
4. 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.
5. American Academy of Dermatology. Guidelines of Care for Soft Tissue Augmentation: Collagen Implants. 1996, Accessed 02/03/2003 1996.
6. American Medical Association. *Current Procedural Terminology (CPT ®)*.
7. American Podiatric Medical Association. Freezing Temperatures Becoming Popular Method for Treating Chronic Pain. Accessed 06/25/08.
8. ArthroCare® Corporation. Topaz Info Fascia. Accessed 06/18/2010.
9. BCBS Association Technology Assessment Program. Extracorporeal Shock Wave Treatment for Chronic Plantar Fasciitis. 03/2005;19(18).
10. BlueCross BlueShield of AZ. *Benefit Plan Booklet*.
11. Buchbinder R, Ptaszniak 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.
12. California Technology Assessment Forum. Extracorporeal Shock Wave Therapy for Plantar Fasciitis. *Blue Shield of California Foundation.* 02/13/2002 2002.



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Resources: (cont.)

13. California Technology Assessment Forum. Extracorporeal Shock Wave Therapy (ESWT) for Plantar Fasciitis Not Responding to Conservative Therapy. *Blue Shield of California Foundation*. 06/20/2007 2007.
14. California Technology Assessment Forum. Extracorporeal Shock Wave Therapy (ESWT) for Plantar Fasciitis Not Responding to Conservative Therapy. *Blue Shield of California Foundation*. 10/28/2009 2009.
15. Cavazos GJ, Khan KH, D'Antoni AV, Harkless LB, Lopez D. Cryosurgery for the treatment of heel pain. *Foot Ankle Int*. Jun 2009;30(6):500-505.
16. Fallat L. Chronic Plantar Fasciitis: Is Cryosurgery the Answer? *Podiatry Today*. 05/2005 2005.
17. Ferguson K, Thomson AG, Moir JS. Case study: Epidermoid cyst following percutaneous Topaz coblation for plantar fasciitis. *Foot (Edinb)*. Mar 2012;22(1):46-47.
18. Goldstein SH. Cryosurgery for the Treatment of Tarsal Tunnel Syndrome. *Podiatry Management*. 2006 Oct 2006.
19. Healey K, Chen K. Plantar fasciitis: current diagnostic modalities and treatments. *Clin Podiatr Med Surg*. Jul 2010;27(3):369-380.
20. 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.
21. Lambariski D, Wendelken ME. A New Approach To Treating Painful Diabetic Neuropathy. *Podiatry Today*. 2007 Jan 2007.
22. 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.
23. Practice Management Information Corporation. *Health Care Procedure Coding System (HCPCS)*. 2005 2005.
24. Practice Management Information Corporation. *International Classification of Diseases (ICD-9-CM)*. 2005 2005.
25. 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.



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Resources: (cont.)

26. 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.
27. Szabo G, Marcsik A, Farkas C. [Results of patient information and of a therapeutic exercise program in the treatment of plantar fasciitis]. *Orv Hetil.* Apr 25 2010;151(17):698-701.
28. 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.
29. Theodore GH, Buch M, Amendola A, Bachmann C, Fleming LL, Zingas C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. *Foot Ankle Int.* 2004 May 2004;25(5):290-297.
30. Weil LJ, Glover JP, Weil LSS. A new minimally invasive technique for treating plantar fasciosis using bipolar radiofrequency: a prospective analysis. *Foot Ankle Spec.* 2008 Feb 2008;1(1):13-18.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Dii kwe'é atah nilínigíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idílkidgo éi doodago Háida bijá anilyeedígíí t'áadoo le'é yina'idílkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowotgo bee haz'á doo baqah ilínigóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您、或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

