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
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.
FOOT DISORDER TREATMENTS (cont.)

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, “Radiofrequency 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.
FOOT DISORDER TREATMENTS (cont.)

Criteria: (cont.)

Neuroablation: (cont.)

- 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.

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.


FOOT DISORDER TREATMENTS (cont.)

Resources: (cont.)


10. BlueCross BlueShield of AZ. *Benefit Plan Booklet.*


FOOT DISORDER TREATMENTS (cont.)

Resources: (cont.)


FOOT DISORDER TREATMENTS (cont.)

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 filling 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: Díi kwe’é atah niilinígíí Blue Cross Blue Shie’d of Arizona haada yit’éego bina’idíilkidgo éi dooçaag Háída bijá aniyeedííí ti’áadoo le’é yiína’idíilkidgo beehaz’aanii hólo díí t’áá hazaadk’ehi háká a’doowólogo bee haz’á doo báah ilínígó. Atá’ halne’ígíí ko’jí bíchí’jí hodilín há 877-475-4799.

Chinese: 如果您，或是您正在协助的对象，有关于插入项目的内容 Blue Cross Blue Shield of Arizona 方面的问题，您有权利免费以您的母语得到帮助和讯息。洽询一位翻译员，请拨电话，在此插入数字 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 thợ dịch viễn, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تসاعد أسلحة يتخصص في الفنون المعمارية،_blue cross blue shield of arizona_، فليس عليك أن تدفع بكمينةيد (877) 475-4799.
FOOT DISORDER TREATMENTS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay maaaring magkaroon ng prehensyon ang Blue Cross Blue Shield of Arizona, maisagawa ka na makakuha ng tulungan at impormasyon sa iyong wika ng walang gastos. Upang makuasa ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 퀘어 또는 퀘어가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 퀘어는 그러한 도움과 정보를 퀘어의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 전화하십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Doimetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лице, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi:

Farsi:

Assyrian:

Serbo-Croatian: Ukoiko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่เสียเงิน โทร 877-475-4799