BlueCross BlueShield Arizona

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EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 09/19/22**
SECTION: SURGERY	**LAST REVIEW DATE: 08/16/22**
	CURRENT EFFECTIVE DATE: 09/19/22
	LAST CRITERIA REVISION DATE:
NEXT ANNUAL REVIEW DATE: 3RD QTR 2023	**ARCHIVE DATE:**

SYNTHETIC CARTILAGE IMPLANTS FOR JOINT PAIN

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 Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria 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.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

SYNTHETIC CARTILAGE IMPLANTS FOR JOINT PAIN (cont.)

Description:

Articular cartilage damage, either from a focal lesion or diffuse osteoarthritis (OA), can result in disabling pain. Cartilage is a hydrogel, comprised mostly of water with collagen and glycosaminoglycans, that does not typically heal on its own. There is a need for improved treatment options. In 2016, a synthetic polyvinyl alcohol hydrogel disc received marketing approval by the U.S. Food and Drug Administration for the treatment of degenerative or posttraumatic arthritis in the first metatarsophalangeal (MTP) joint. If proven successful for the treatment of the MTP joint, off-label use is likely.

Articular Cartilage Damage
Articular cartilage damage may present as focal lesions or as more diffuse osteoarthritis. Cartilage is a biological hydrogel that is comprised mostly of water with collagen and glycosaminoglycans and does not typically heal on its own. Osteoarthritis or focal articular cartilage lesions can be associated with substantial pain, loss of function, and disability. Osteoarthritis is most frequently observed in the knees, hips, interphalangeal joints, first carpometacarpal joints, first metatarsophalangeal (MTP) joint, and apophyseal (facet) joints of the lower cervical and lower lumbar spine. Osteoarthritis less commonly affects the elbow, wrist, shoulder, and ankle. Knee osteoarthritis is the most common cause of lower-limb disability in adults over age 50, however, osteoarthritis of the MTP joint with loss of motion (hallux rigidus) can also be severely disabling due to pain in the “toe-off” position of gait. An epidemiologic study found that osteoarthritis of the first MTP joint may be present in as many as 1 in 40 people over the age of 50.

Treatment
Treatment may include debridement, abrasion techniques, osteochondral autografting, and autologous chondrocyte implantation. Debridement involves the removal of the synovial membrane, osteophytes, loose articular debris, and diseased cartilage and is capable of producing symptomatic relief. Subchondral abrasion techniques attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. Diffuse osteoarthritis of the knee, hip, shoulder or ankle may be treated with joint replacement.

Early-stage osteoarthritis of the first MTP joint is typically treated with conservative management, including pain medication and change in footwear. Failure of conservative management in individuals with advanced osteoarthritis of the MTP joint may be treated surgically. Cheliectomy (removal of bone osteophytes) and interpositional spacers with autograft or allograft have been used as temporary measures to relieve pain.

Although partial or total joint replacement have been explored for MTP osteoarthritis, complications from bone loss, loosening, wear debris, implant fragmentation, and transfer metatarsalgia are not uncommon. Also, since the conversion of a failed joint replacement to arthrodesis has greater complications and worse functional results than a primary arthrodesis (joint fusion), MTP arthrodesis is considered the most reliable and primary surgical option. Arthrodesis can lead to a pain-free foot, but the loss of mobility in the MTP joint alters gait, may restrict participation in running and other sports, and limits footwear options, leading to individual dissatisfaction. Transfer of stress and arthritis in an adjacent joint may also develop over time.

SYNTHETIC CARTILAGE IMPLANTS FOR JOINT PAIN (cont.)

Description: (cont.)

Because of the limitations of MTP arthrodesis, alternative treatments that preserve joint motion are being explored. Synthetic cartilage implants have been investigated as a means to reduce pain and improve function in individuals with hallux rigidus. Some materials such as silastic were found to fragment with use. Other causes of poor performance are the same as those observed with metal and ceramic joint replacement materials and include dislocation, particle wear, osteolysis, and loosening.

Synthetic polyvinyl alcohol (PVA) hydrogels have water content and biomechanical properties similar to cartilage and they are biocompatible. Polyvinyl alcohol hydrogels have been used in a variety of medical products including soft contact lens, artificial tears, hydrophilic nerve guides, and tissue adhesion barriers. This material is being evaluated for cartilage replacement due to the rubber elastic properties and, depending on the manufacturing process, high tensile strength and compressibility.

The Cartiva implant is an 8- to 10 mm PVA disc that is implanted with a slight protrusion to act as a spacer for the first MTP joint. It comes with dedicated reusable instrumentation, which includes a drill bit, introducer, and placer.

The Cartiva PVA implant was approved by the U.S. Food and Drug Administration (FDA) in 2016 for the treatment of arthritis of the MTP joint. It has been distributed commercially since 2002 with approval in Europe, Canada, and Brazil. The Cartiva Synthetic Cartilage Implant was approved by the FDA through the premarket approval process (P150017) for painful degenerative or posttraumatic arthritis in the first MTP joint along with hallux valgus or hallux limitus and hallux rigidus. Lesions greater than 10 mm in size and insufficient quality or quantity of bone are contraindications.

Criteria:

- Synthetic cartilage implants for the treatment of articular cartilage damage are considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement outside the investigational setting.

SYNTHETIC CARTILAGE IMPLANTS FOR JOINT PAIN (cont.)

Resources:

Literature reviewed 08/16/22. We do not include marketing materials, poster boards and non-published literature in our review.

1. An TW, Cassinelli S, Charlton TP, Pfeffer GB, Thordarson DB. Radiographic and Magnetic Resonance Imaging of the Symptomatic Synthetic Cartilage Implant. *Foot Ankle Int*. Jan 2020;41(1):25-30. doi:10.1177/1071100719877147

2. Baker MI, Walsh SP, Schwartz Z, Boyan BD. A review of polyvinyl alcohol and its uses in cartilage and orthopedic applications. *J Biomed Mater Res B Appl Biomater*. Jul 2012;100(5):1451-7. doi:10.1002/jbm.b.32694

3. Baumhauer JF, Singh D, Glazebrook M, et al. Prospective, Randomized, Multi-centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus. *Foot Ankle Int*. May 2016;37(5):457-69. doi:10.1177/1071100716635560

4. Baumhauer JF, Singh D, Glazebrook M, et al. Correlation of Hallux Rigidus Grade With Motion, VAS Pain, Intraoperative Cartilage Loss, and Treatment Success for First MTP Joint Arthrodesis and Synthetic Cartilage Implant. *Foot Ankle Int*. Nov 2017;38(11):1175-1182. doi:10.1177/1071100717735289

5. Cassinelli SJ, Chen S, Charlton TP, Thordarson DB. Early Outcomes and Complications of Synthetic Cartilage Implant for Treatment of Hallux Rigidus in the United States. *Foot Ankle Int*. Oct 2019;40(10):1140-1148. doi:10.1177/1071100719855049

6. Glazebrook M, Baumhauer JF, Blundell C, et al. Letter Regarding: Early Outcomes and Complications of Synthetic Cartilage Implant for Treatment of Hallux Rigidus in the United States. *Foot Ankle Int*. Oct 2019;40(10):1149-1151. doi:10.1177/1071100719878414

7. Glazebrook M, Blundell CM, O'Dowd D, et al. Midterm Outcomes of a Synthetic Cartilage Implant for the First Metatarsophalangeal Joint in Advanced Hallux Rigidus. *Foot Ankle Int*. Apr 2019;40(4):374-383. doi:10.1177/1071100718815469

8. Glazebrook M, Younger ASE, Daniels TR, et al. Treatment of first metatarsophalangeal joint arthritis using hemiarthroplasty with a synthetic cartilage implant or arthrodesis: A comparison of operative and recovery time. *Foot Ankle Surg*. Oct 2018;24(5):440-447. doi:10.1016/j.fas.2017.05.002

9. Goldberg A, Singh D, Glazebrook M, et al. Association Between Patient Factors and Outcome of Synthetic Cartilage Implant Hemiarthroplasty vs First Metatarsophalangeal Joint Arthrodesis in Advanced Hallux Rigidus. *Foot Ankle Int*. Nov 2017;38(11):1199-1206. doi:10.1177/1071100717723334

SYNTHETIC CARTILAGE IMPLANTS FOR JOINT PAIN (cont.)

Resources: (cont.)

10. Gould N, Schneider W, Ashikaga T. Epidemiological survey of foot problems in the continental United States: 1978-1979. *Foot Ankle*. Jul 1980;1(1):8-10. doi:10.1177/107110078000100104

11. Joo PY, Baumhauer JF, Waldman O, et al. Physical Function and Pain Interference Levels of Hallux Rigidus Patients Before and After Synthetic Cartilage Implant vs Arthrodesis Surgery. *Foot Ankle Int*. Oct 2021;42(10):1277-1286. doi:10.1177/10711007211007843

12. Metikala S, Mahmoud K, O'Connor KM, Chao W, Wapner KL, Farber DC. Adverse Events Related to Cartiva Hemiarthroplasty of First Metatarsal: An Analysis of Reports to the United States Food and Drug Administration. *Foot Ankle Spec*. Jul 29 2020:1938640020943715. doi:10.1177/1938640020943715

13. Shi E, Todd N, Rush S, et al. First Metatarsophalangeal Joint Space Area Decreases Within 1 Month After Implantation of a Polyvinyl Alcohol Hydrogel Implant: A Retrospective Radiographic Case Series. *J Foot Ankle Surg*. Nov 2019;58(6):1288-1292. doi:10.1053/j.jfas.2019.04.007

14. Smyth NA, Murawski CD, Hannon CP, Kaplan JR, Aiyer AA. The Use of a Synthetic Cartilage Implant for Hallux Rigidus: A Systematic Review. *Foot Ankle Spec*. Aug 2021;14(4):366-371. doi:10.1177/1938640020937160

15. Thordarson DB, Cassinelli SJ, Charlton TP, Chen S. Response to "Letter Regarding: Early Outcomes and Complications of Synthetic Cartilage Implant for Treatment of Hallux Rigidus in the United States". *Foot Ankle Int*. Oct 2019;40(10):1152-1153. doi:10.1177/1071100719878413

16. U.S. Food and Drug Administration. Cartiva: Post approval studies. 2016. Accessed June 5, 2020. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?c_id=4019&t_id=570803

17. U.S. Food and Drug Administration. Cartiva: Summary of Safety and Effectiveness. 2016. Accessed June 5, 2020. https://www.accessdata.fda.gov/cdrh_docs/pdf15/p150017b.pdf

Coding:

CPT: 28291

HCPCS: L8641, L8642, L8699

SYNTHETIC CARTILAGE IMPLANTS FOR JOINT PAIN (cont.)

History:	Date:	Activity:
Medical Policy Panel	08/16/22	Approved guideline (Effective 9/19/22)
Medical Director (Dr. Deering)	07/10/22	Development

Policy Revisions:

SYNTHETIC CARTILAGE IMPLANTS FOR JOINT PAIN (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 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: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojį' bich'į' 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 تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

SYNTHETIC CARTILAGE IMPLANTS FOR JOINT PAIN (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 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 Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, 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:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
[تماس حاصل نمایید.

Assyrian:

[illegible] Blue Cross Blue Shield of Arizona [illegible] 877-475-4799.

Serbo-Croatian: Ukoliko 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: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799