BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 07/11/17**
SECTION: SURGERY	**LAST REVIEW DATE: 05/15/18**
	LAST CRITERIA REVISION DATE: 05/15/18
	ARCHIVE DATE:

AUTOGRAFTS AND ALLOGRAFTS IN THE TREATMENT OF FOCAL ARTICULAR CARTILAGE LESIONS

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.

AUTOGRAFTS AND ALLOGRAFTS IN THE TREATMENT OF FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Description:

Allogeneic and Autologous Osteochondral Grafts:
Chondral and osteochondral grafts replace damaged or destroyed articular cartilage with healthy articular cartilage from a cadaver (allograft) or from the individual (autograft). A plug of bone with healthy cartilage attached is harvested from a non-weight-bearing area of the individual's own femoral condyles and inserted into tunnels that have been prepared in the area of the damaged or destroyed cartilage. If the defect is large, an osteochondral allograft is performed using a suitable cadaver donor.

Allogeneic and Autologous Minced Cartilage:
Allogeneic and autologous minced cartilage have been investigated for repair of damaged articular cartilage. Products include BioCartilage® and DeNovo NT Graft.

Decellularized Osteochondral Allograft Plugs:
Chondrofix® has been investigated for the repair of osteochondral articular cartilage defects. It is a minimally processed osteochondral allograft composed of decellularized hyaline cartilage and cancellous bone. It can be used "off the shelf" with precut cylinders (7-15 mm). Multiple cylinders may be used to fill a larger defect.

Reduced Osteochondral Allograft Discs:
ProChondrix® and Cartiform® are wafer-thin allografts where the bony portion of the allograft is reduced. The discs are laser etched or porated and contain hyaline cartilage with chondrocytes, growth factors and extracellular matrix proteins. The discs are typically inserted after microfracture and secured in place with fibrin glue and/or sutures. DeNovo ET graft uses juvenile allogeneic cartilage cells. ProChondrix, Cartiform and DeNovo ET have been investigated for the repair of osteochondral articular cartilage defects.

Synthetic Bone Fillers:

Synthetic resorbable polymers, such as PolyGraft®, are polymer scaffolds that have been investigated for the repair of osteochondral articular cartilage defects. The implant functions as a scaffold for chondral and osteogenic cells with the synthetic polymer being resorbed as the cells produce their normal matrices.

According to the FDA label indications, PolyGraft can be used to fill bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure and may be combined with autogenous blood products, such as platelet rich plasma, and/or sterile fluids, such as saline or Ringer's solution. Several products which contain the PolyGraft material include, *but are not limited to*, TruGraft® granules, TruFit® CB Plugs and TruFit® Bone Graft Substitute (BGS) plugs.

AUTOGRAFTS AND ALLOGRAFTS IN THE TREATMENT OF FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Criteria:

All requests will be reviewed by the medical director(s) and/or clinical advisor(s).

- Osteochondral fresh allografting is considered ***medically necessary*** as a technique to repair **ONE** of the following:

  1. Full thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (e.g., microfracture, osteochondrial autografting or autologous chondrocyte implantation) would be inadequate due to size, location, or depth of the lesion
  2. Large (area >1.5 cm_2) or cystic (volume >3.0 cm_3) osteochondral lesions of the talus when autografting would be inadequate due to the size, depth or location of the lesion
  3. Revision surgery after failed prior marrow stimulation for large (area >1.5 cm_2) or cystic (volume >3.0 cm_3) osteochondral lesions of the talus when autografting would be inadequate due to size, depth or location of the lesion.

- Osteochondral autografting using one or more cores of osteochondral tissue is considered ***medically necessary*** with documentation of **ONE** of the following:

  1. For the treatment of symptomatic full-thickness cartilage defects of the knee caused by acute or repetitive trauma in individuals who have had an inadequate response to a prior surgical procedure with documentation of **ALL** of the following:

     - Age 15 to 55 years
     - Focal, full-thickness (grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles, trochlea, or patella that are 1.0 cm squared or greater in total area
     - Minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less), and normal-appearing hyaline cartilage surrounding the border of the defect
     - Normal knee biomechanics or alignment and stability achieved concurrently with osteochondral grafting

  2. Large (area >1.5 cm2) or cystic (volume >3.0 cm3) osteochondral lesions of the talus
  3. Revision surgery after failed marrow stimulation for osteochondral lesion of the talus

- Osteochondral autografting or allografting for all other indications not previously listed or if above criteria not met 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.

AUTOGRAFTS AND ALLOGRAFTS IN THE TREATMENT OF FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Criteria: (cont.)

- The following treatments of focal articular cartilage lesions 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  These treatments include*, but are not limited to*:
  - Allogeneic minced or particulated cartilage
  - Autologous minced or particulated cartilage
  - Decellularized osteochondral allograft plugs (e.g., Chondrofix)
  - Reduced osteochondral allograft discs (e.g., ProChondrix, Cartiform)

- The following products to repair osteochondral articular cartilage defects 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  These products include*, but are not limited to*:
  - PolyGraft
  - TruFit Bone Graft Substitute (BGS) Plugs
  - TruFit CB Plugs
  - TruGraft Granules

AUTOGRAFTS AND ALLOGRAFTS IN THE TREATMENT OF FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Resources:

Literature reviewed 05/15/18. 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.

Resources prior to 07/10/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.78 BCBS Association Medical Policy Reference Manual. Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions. Re-issue date 04/12/2018, issue date 08/15/2001.

2. Azam A, Forster M, Robertson A. Clinical and radiological outcome for Trufit Plug in the treatment of chondral and osteochondral lesions at a minimum of 2 years. *Journal of orthopaedics.* Mar 2018;15(1):47-51.

3. Bugelli G, Ascione F, Dell'Osso G, Zampa V, Giannotti S. Biphasic bioresorbable scaffold (TruFit((R))) in knee osteochondral defects: 3-T MRI evaluation of osteointegration in patients with a 5-year minimum follow-up. *Musculoskeletal surgery.* Nov 21 2017.

4. Clinical Trials.Gov. Smith & Nephew's European Trufit Study. Accessed 05/08/2018, 06/19/2017, 06/18/2013.

5. Dell'Osso G, Bottai V, Bugelli G, et al. The biphasic bioresorbable scaffold (Trufit((R))) in the osteochondral knee lesions: long-term clinical and MRI assessment in 30 patients. *Musculoskeletal surgery.* Aug 2016;100(2):93-96.

6. Dhollander AA, Liekens K, Almqvist KF, et al. A pilot study of the use of an osteochondral scaffold plug for cartilage repair in the knee and how to deal with early clinical failures. *Arthroscopy.* Feb 2012;28(2):225-233.

7. Di Cave E, Versari P, Sciarretta F, Luzon D, Marcellini L. Biphasic bioresorbable scaffold (TruFit Plug((R))) for the treatment of osteochondral lesions of talus: 6- to 8-year follow-up. *Foot (Edinburgh, Scotland).* Dec 2017;33:48-52.

8. Fraser EJ, Savage-Elliott I, Yasui Y, et al. Clinical and MRI Donor Site Outcomes Following Autologous Osteochondral Transplantation for Talar Osteochondral Lesions. *Foot & ankle international.* Sep 2016;37(9):968-976.

AUTOGRAFTS AND ALLOGRAFTS IN THE TREATMENT OF FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Resources: (cont.)

9. Hindle P, Hendry JL, Keating JF, Biant LC. Autologous osteochondral mosaicplasty or TruFit plugs for cartilage repair. *Knee Surg Sports Traumatol Arthrosc.* Apr 16 2013.

10. Joshi N, Reverte-Vinaixa M, Diaz-Ferreiro EW, Dominguez-Oronoz R. Synthetic resorbable scaffolds for the treatment of isolated patellofemoral cartilage defects in young patients: magnetic resonance imaging and clinical evaluation. *Am J Sports Med.* Jun 2012;40(6):1289-1295.

11. Smith & Nephew Inc. Trufit CB Plugs and TruFit Bone Graft Substitute (BGS) Plugs. Accessed 06/19/2017.

12. Verhaegen J, Clockaerts S, Van Osch GJ, Somville J, Verdonk P, Mertens P. TruFit Plug for Repair of Osteochondral Defects-Where Is the Evidence? Systematic Review of Literature. *Cartilage.* Jan 2015;6(1):12-19.

AUTOGRAFTS AND ALLOGRAFTS IN THE TREATMENT OF FOCAL ARTICULAR CARTILAGE LESIONS (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 íłínígóó. 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.

AUTOGRAFTS AND ALLOGRAFTS IN THE TREATMENT OF FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

<u>Multi-Language Interpreter Services</u>: (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]
[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