MEDICAL COVERAGE GUIDELINES

SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 07/10/13
LAST REVIEW DATE: 05/23/17
LAST CRITERIA REVISION DATE: 05/23/17
ARCHIVE DATE:

AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR 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.

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AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Description:

Damaged articular cartilage typically fails to heal on its own and can be associated with pain, loss of function, and disability and may lead to debilitating osteoarthritis over time. The manifestations can severely impair an individual’s activities of daily living and adversely affect quality of life.

Conventional treatment options include debridement, subchondral drilling, microfracture, and abrasion arthroplasty. Osteochondral grafts and autologous chondrocyte implantation (ACI) attempt to regenerate hyaline-like cartilage and thereby restore durable function.

With ACI, a region of healthy cartilage is identified and biopsied through arthroscopy. The tissue is sent to a facility licensed by the U.S Food and Drug Administration (FDA) where it is minced and enzymatically digested, and the chondrocytes are separated by filtration. The isolated chondrocytes are cultured for 11-21 days to expand the cell population, tested, and then shipped back for implantation. With the individual under general anesthesia, an arthrotomy is performed, and the chondral lesion is excised up to the normal surrounding cartilage. Methods to improve the first-generation ACI procedure have been developed, including the use of a scaffold or matrix-induced autologous chondrocyte implantation (MACI) composed of biocompatible carbohydrates, protein polymers, or synthetics. The only FDA-approved MACI product to date is supplied in a sheet, which is cut to size and fixed with fibrin glue. This procedure is considered technically easier and less time consuming than the first-generation technique, which required suturing of a periosteal or collagen patch and injection of chondrocytes under the patch.

The culturing of chondrocytes is considered by the U.S. Food and Drug Administration (FDA) to fall into the category of manipulated autologous structural (MAS) cells which are subject to a biologic licensing requirement. In 1997, Carticel® (Genzyme; now Vericel) has received FDA approval for the culturing of chondrocytes through a biologics license. In December 2016, MACI® (Vericel), a matrix-induced ACI, received FDA approval. MACI consists of autologous chondrocytes which are cultured into a bioresorbable porcine-derived collagen membrane. In 2017, production of Carticel® was phased out and MACI is the only ACI product that is available in the United States.
AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Criteria:

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

- Autologous chondrocyte implantation for the repair of symptomatic, cartilaginous defects of the patella or femoral condyle at the knee (medial, lateral or trochlear) caused by acute or repetitive trauma is considered medically necessary with documentation of ALL of the following:
  
  1. Individual is between 15 and 55 years of age
  2. ONE of the following significant symptoms:
     - Pain
     - Limitation of daily or recreational activities that have lasted greater than 1 year
     - Locking or “catching”
     - Swelling
  3. Other treatments have failed
  4. Knee is stable with normal alignment
  5. Cartilage defect is 1.5 cm or greater (arthroscopic photograph of defect must be submitted)
  6. Minimal or no evidence of osteoarthritis, degenerative joint disease or inflammatory joint disease (Defined as grade II degeneration or less)
  7. Other parts of the knee, including the patellofemoral joint and tibial articular cartilage are diagnosed as normal

- Autologous chondrocyte implantation for the treatment of osteochondritis dissecans of the knee is considered medically necessary with documentation that lesion is 7mm or less in depth.

- Autologous chondrocyte implantation 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

- Autologous chondrocyte implantation for all other joints (e.g., talar, ankle, hip) is considered experimental or investigational based upon insufficient scientific evidence to permit conclusions concerning the effect on health outcomes.
AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Resources:

Literature reviewed 05/23/17. 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.

AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR 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/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 nilínigíí Blue Cross Blue Shield of Arizona haadá yít’éego bíná’ídiilikígo éí doocdagó Háída bijá aniyeedíí t’áá doodoo le’é yina’ídiilikígo beeheaz’áainii hóółt díí t’áá hazaadk’ehjí háká a’doowolgo bee haz’á doo bqáhh ilínígóó. Atha’ halne’ilgíi kojí bíchjí’ hodilíhin 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 thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thành viên dịch vụ, xin gọi 877-475-4799.

Arabic: إن كان لديك أو أدى شخص تساؤل أسئلة بشأن ممارسات الضرورية بلغتك من دون اية تكلفة، للتحدث مع مترجم يصلب ب 877-475-4799.
AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tunawigangan, 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 Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 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 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 اطلاعات به بیان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian: ، ، Blue Cross Blue Shield of Arizona ئەگەر شەوەیە کە شەوەیە نەوەکەیە، سەوەیە به بەدەمەیە، یەکە لە ەاتەکەیە، یەکە لە ەاتەکەیە، 877-475-4799.

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 prevodocem, nazovite 877-475-4799.

Thai: หากคุณ หรือครอบครัวของคุณมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถได้รับความช่วยเหลือและข้อมูลในภาษาของคุณได้โดยไม่เสียค่าใช้จ่าย หลังจากนี้ โทร 877-475-4799