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## OVERVIEW

A variety of procedures are being developed to resurface articular cartilage defects. Autologous chondrocyte implantation (ACI) involves harvesting chondrocytes from healthy tissue, expanding the cells in vitro, and implanting the expanded cells into the chondral defect. Second- and third-generation techniques include combinations of autologous chondrocytes, scaffolds, and growth factors. This policy addresses autologous chondrocyte implantation (ACI).

## MEDICAL CRITERIA

### BlueCHiP for Medicare and Commercial Products

Autologous chondrocyte implantation may be considered **medically necessary** for the treatment of disabling full-thickness articular cartilage defects of the knee caused by acute or repetitive trauma, when all of the following criteria are met:

- Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years)
- Focal, full-thickness (grade III or IV) unipolar lesions of the weight bearing surface of the femoral condyles, trochlea or patella at least 1.5 cm<sup>2</sup> in size
- Documented 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

## PRIOR AUTHORIZATION

### BlueCHiP for Medicare and Commercial Products

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products and obtained via the online tool for participating providers. See the Related Policies section.

## POLICY STATEMENT

### BlueCHiP for Medicare and Commercial Products

Autologous chondrocyte transplantation for the treatment of cartilage defects of the knee is considered medically necessary when medical criteria are met.

Autologous chondrocyte implantation for all other joints, including the talar, and any indications other than those listed above is considered not medically necessary, as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery benefits/coverage.

## BACKGROUND

### ARTICULAR CARTILAGE LESIONS

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. These manifestations can severely impair a patient's activities of daily living and adversely affect quality of life.

#### Treatment

Conventional treatment options include débridement, subchondral drilling, microfracture, and abrasion arthroplasty. Débridement involves the removal of synovial membrane, osteophytes, loose articular debris, and diseased cartilage and is capable of producing symptomatic relief. Subchondral drilling, microfracture, and abrasion arthroplasty attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. Compared with the original hyaline cartilage, fibrocartilage has less capability to withstand shock or shearing force and can degenerate over time, often resulting in the return of clinical symptoms. Osteochondral grafts and autologous chondrocyte implantation (ACI) attempt to regenerate hyaline-like cartilage and thereby restore durable function. Osteochondral grafts for the treatment of articular cartilage defects are not discussed in this policy.

With ACI, a region of healthy articular 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 to 21 days to expand the cell population, tested, and then shipped back for implantation. With the patient 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.

Desired features of articular cartilage repair procedures are the ability (1) to be implanted easily, (2) to reduce surgical morbidity, (3) not to require harvesting of other tissues, (4) to enhance cell proliferation and maturation, (5) to maintain the phenotype, and (6) to integrate with the surrounding articular tissue. In addition to the potential to improve the formation and distribution of hyaline cartilage, use of a scaffold with ACI eliminates the need for harvesting and suture of a periosteal or collagen patch. A scaffold without cells may also support chondrocyte growth.

The culturing of chondrocytes is considered by FDA to fall into the category of manipulated autologous structural cells, which are subject to a biologic licensing requirement. In 1997, Carticel® (Genzyme; now Vericel) received FDA approval for the repair of clinically significant, "...symptomatic cartilaginous defects of the femoral condyle (medial lateral or trochlear) caused by acute or repetitive trauma...."

In December 2016, MACI® (Vericel), received FDA approved for "the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults." MACI® consists of autologous chondrocytes which are cultured onto a bioresorbable porcine-derived collagen membrane. In 2017, production of Carticel® was phased out and MACI® is the only ACI product available in the United States.

The entire matrix-induced ACI procedure consists of 4 steps: (1) initial arthroscopy and biopsy of normal cartilage, (2) culturing of chondrocytes on an absorbable collagen matrix, (3) a separate arthrotomy to place the implant, and (4) postsurgical rehabilitation. The initial arthroscopy may be scheduled as a diagnostic procedure; as part of this procedure, a cartilage defect may be identified, prompting biopsy of normal cartilage in anticipation of a possible chondrocyte transplant. The biopsied material is then sent for culturing and returned to the hospital when the implantation procedure (ie, arthrotomy) is scheduled.

For individuals who have focal articular cartilage lesions of joints other than the knee who receive ACI, the evidence is insufficient to determine the effects of the technology on health outcomes.

## **CODING**

### **BlueCHIP for Medicare and Commercial Products**

The following codes are covered when the medical criteria above have been met:

There is a specific CPT category I code for ACI of the knee:

**27412** Autologous chondrocyte implantation, knee

HCPCS supply code for the autologous cultured chondrocyte implant:

**J7330** Autologous cultured chondrocytes, implant

## **RELATED POLICIES**

Preauthorization via Web-Based Tool for Procedures

## **PUBLISHED**

Provider Update, August 2017

Provider Update, September 2017

Provider Update, October 2016

Provider Update, January 2016

Provider Update, January 2015

Provider Update, July 2013

Provider Update, May 2012

## **REFERENCES**

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4. Blue Cross and Blue Shield Association Technology Evaluation Center. Autologous chondrocyte transplantation of the knee. TEC Assessment. 2003;Volume 18:Tab 2.
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6. Devitt BM, Bell SW, Webster KE, et al. Surgical treatments of cartilage defects of the knee: Systematic review of randomised controlled trials. *Knee.* Jun 2017;24(3):508-517. PMID 28189406
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