

Medical Coverage Policy | Autologous Chondrocyte Implantation



EFFECTIVE DATE: 01|01|2016

POLICY LAST UPDATED: 11|03|2015

OVERVIEW

A variety of procedures are being developed to resurface articular cartilage defects. 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, in patients who have had an inadequate response to a prior surgical procedure, 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 on the weight bearing surface of the femoral condyles or trochlea at least 1.5 cm² 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.

There is no scientific literature to support the use of autologous chondrocyte implantation for all other joints, including patellar and talar, or any indications other than those listed above, therefore all other indications are considered **not medically necessary**.

Matrix-induced autologous chondrocyte implantation is considered not medically necessary due to insufficient peer-reviewed scientific literature proving the efficacy of the service.

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

Autologous chondrocyte implantation (ACI) involves harvesting chondrocytes from healthy tissue, expanding the cells in vitro, and implanting the expanded cells into the chondral defect under a periosteal or fibrin patch. Second- and third-generation techniques include combinations of autologous chondrocytes, scaffolds, and growth factors.

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 an individual's activities of daily living and adversely affect quality of life. Conventional treatment options include debridement, subchondral drilling, microfracture, and abrasion arthroplasty. Debridement 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 to 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 ACI attempt to regenerate hyaline-like cartilage and thereby restore durable function.

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 11–21 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. A periosteal flap is removed from the proximal medial tibia and sutured to the surrounding rim of normal cartilage. The cultured chondrocytes are then injected beneath the periosteal flap. ACI may be considered more effective for larger lesions than microfracture or osteochondral grafts, but it is technically difficult, requiring 2 procedures and harvesting of periosteum. In addition, use of the FDA-indicated periosteal cover may result in hypertrophy, as well as donor-site morbidity.

The entire ACI procedure consists of 4 steps: 1) the initial arthroscopy and biopsy of normal cartilage, 2) culturing of chondrocytes, 3) a separate arthrotomy to create a periosteal flap and implant the chondrocytes, and 4) post-surgical 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 (i.e., arthrotomy) is scheduled.

The culturing of chondrocytes is considered by the FDA to fall into the category of manipulated autologous structural (MAS) cells, which are subject to a biologic licensing requirement. At the present time, only Carticel™ (Genzyme) has received FDA approval for the culturing of chondrocytes through a biologics license.

Although evidence from long-term studies is still accumulating, current evidence indicates that ACI can improve symptoms in some patients with lesions of the articular cartilage of the knee who have failed prior surgical treatment. These patients, who are too young for total knee replacement, have limited options. Therefore, based on the clinical input, highly suggestive evidence from randomized controlled trials and prospective observational studies, it is concluded that ACI may be considered an option for the FDA-approved indication of disabling full-thickness chondral lesions of the femoral condyles or trochlea caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior procedure. Additional studies are needed to evaluate whether marrow stimulation at the time of biopsy affects implant success. Recent evidence indicates that ACI combined with meniscal allograft results in outcomes similar to either procedure performed alone; therefore, combined procedures may be considered medically necessary.

Evidence is currently insufficient to evaluate the efficacy of ACI in comparison with other surgical repair procedures as a primary treatment of large lesions or to evaluate the efficacy of ACI for the patella or for joints other than the knee, therefore, this is considered not medically necessary.

Results from second generation ACI procedures (matrix-induced ACI [MACI]) from Europe appear promising. These products use a variety of biodegradable scaffolds and have the potential to improve consistent hyaline cartilage formation and reduce complications associated with injection under a periosteal patch. To date, there are a smaller number of randomized controlled trials with short-term follow-up comparing MACI with ACI, and no MACI products are approved in the U.S.; therefore, these are considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

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

CPT code for Carticel™ implantation:
27412

HCPCS supply code:
J7330

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, January 2016
Provider Update, January 2015
Provider Update, July 2013
Provider Update, May 2012
Provider Update, July 2011
Provider Update, September 2009
Provider Update, October 2008

REFERENCES

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Autologous chondrocyte transplantation. TEC Assessments 1996; Volume 11, Tab 8.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Autologous chondrocyte transplantation. TEC Assessments 1997; Volume 12, Tab 26.
3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Autologous chondrocyte transplantation. TEC Assessments 2000; Volume 15, Tab 12.
4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Autologous chondrocyte transplantation of the knee. TEC Assessments 2003; Volume 18, Tab 2.
5. Montgomery SR, Foster BD, Ngo SS, et al. Trends in the surgical treatment of articular cartilage defects of the knee in the United States. *Knee Surg Sports Traumatol Arthrosc.* Sep 2014;22(9):2070-2075. PMID 23896943
6. Mithoefer K, McAdams T, Williams RJ et al. Clinical efficacy of the microfracture technique for articular cartilage repair in the knee: an evidence-based systematic analysis. *Am J Sports Med* Oct 2009; 37(10):2053-63. PMID 19251676
7. Solheim E, Hegna J, Inderhaug E, et al. Results at 10-14 years after microfracture treatment of articular cartilage defects in the knee. *Knee Surg Sports Traumatol Arthrosc.* Nov 23 2014. PMID 25416965

8. Harris JD, Cavo M, Brophy R et al. Biological Knee Reconstruction: A Systematic Review of Combined Meniscal Allograft Transplantation and Cartilage Repair or Restoration. *Arthroscopy* Oct 26 2011; 27(3):409-418. PMID 21030203
9. Knutsen G, Engebretsen L, Ludvigsen TC et al. Autologous chondrocyte implantation compared with microfracture in the knee. A randomized trial. *J Bone Joint Surg Am.* Mar 2004; 86-A(3):455-464. PMID 14996869
10. Knutsen G, Drogset JO, Engebretsen L et al. A randomized trial comparing autologous chondrocyte implantation with microfracture. Findings at five years. *J Bone Joint Surg Am.* Oct 2007; 89(10):2105-2112. PMID 17908884
11. Visna P, Pasa L, Cizmar I et al. Treatment of deep cartilage defects of the knee using autologous chondrograft transplantation and by abrasive techniques--a randomized controlled study. *Acta Chir Belg* Nov-Dec 2004; 104(6):709-714. PMID 15663280
12. Horas U, Pelinkovic D, Herr G et al. Autologous chondrocyte implantation and osteochondral cylinder transplantation in cartilage repair of the knee joint. A prospective, comparative trial. *J Bone Joint Surg Am.* Feb 2003; 85-A(2):185-192. PMID 12571292

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