Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

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Original Effective Date: 8/1/2009
Line(s) of Business: HMO; PPO; QUEST
Current Effective Date: 09/25/2015
Section: Surgery
Place(s) of Service: Inpatient

I. Description
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 under a periosteal or fibrin patch. Second- and third-generation techniques include combinations of autologous chondrocytes, scaffolds, and growth factors.

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 (RCTs) and prospective observational studies, it is concluded that ACI may be considered an option for the U.S. Food and Drug Administration (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.

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 RCTs with short-term follow-up comparing MACI with ACI, and no MACI products are approved in the United States; therefore, these are considered investigational.
II. Criteria/Guidelines

A. ACI is covered (subject to Limitations and Administrative Guidelines) 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:

1. Adolescent patients are skeletally mature with documented closure of growth plates
2. Adult patients that are too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years)
3. 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
4. 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
5. Normal knee biomechanics, or alignment and stability that can be achieved concurrently with ACI
6. Absence of meniscal pathology

III. Limitations

A. If debridement is the only prior surgical treatment, consideration should be given to marrow-stimulating techniques before ACI is performed.

B. Misalignment and instability of the joint are contraindications. Therefore, additional procedures such as repair of ligaments or tendons or creation of an osteotomy for the realignment of the joint may be performed at the same time. If normal knee biomechanics or alignment and stability cannot be achieved concurrently with ACI, the patient is not a good candidate for this surgery.

C. The entire ACI procedure consists of 4 steps: (1) initial arthroscopy and biopsy of normal cartilage, culturing of chondrocytes, a separate arthrotomy to create a periosteal flap and implant the chondrocytes, and 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.

D. The charges for the culturing component of the procedure are submitted as part of the hospital bill.

E. ACI for all other joints, including patellar and talar, and any indications other than those listed above is not covered because it is not known to be effective in improving health outcomes.

F. Matrix-induced autologous chondrocyte implantation is not covered because it is not known to be effective in improving health outcomes.

G. Treatment of focal articular cartilage lesions with autologous minced cartilage is not covered because it is not known to be effective in improving health outcomes.

H. Treatment of focal articular cartilage lesions with allograft, either allogeneic minced cartilage (DeNovo Natural Tissue Graft) or allogeneic cartilage cells (e.g., DeNovo
Engineered Tissue Graft) is not covered because it is not known to be effective in improving health outcomes.

IV. Administrative Guidelines
Precertification is not required. Documentation supporting the medical necessity should be legible and maintained in the patient’s medical record and made available to HMSA upon request. HMSA reserves the right to perform retrospective reviews using the above criteria to validate if services rendered met payment determination criteria.

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V. Important Reminder
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.
Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References