Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Policy Number: MM.06.002
Original Effective Date: 8/1/2009
Line(s) of Business: HMO; PPO; QUEST Integration
Current Effective Date: 03/01/2017
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.

The evidence for ACI for individuals who have focal articular cartilage lesions of the knee includes randomized controlled trials (RCTs) and prospective observational studies. Relevant outcomes are symptoms, functional outcomes, implant survival, quality of life, and resource utilization. Although evidence from long-term studies is still accumulating, current evidence indicates that Food and Drug Administration–approved ACI products can improve symptoms in some patients with lesions of the articular cartilage of the knee. These patients, who are too young for total knee replacement, have limited options. Therefore, ACI may be considered an option for large disabling full-thickness chondral lesions of the knee caused by acute or repetitive trauma. Evidence indicates that a prior surgical procedure may negatively impact the success of ACI, but ACI combined with meniscal allograft results in outcomes similar to either procedure performed alone. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence on ACI for individuals who have focal articular cartilage lesions in joints other than the knee is limited. Relevant outcomes are symptoms, functional outcomes, implant survival, quality of life, and resource utilization. The greatest amount of literature is for ACI of the talus. A systematic review found that outcomes following treatment with ACI were inferior to microfracture. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input was requested on multiple occasions, most recently in 2015 for the use of ACI in the patella. Prior clinical input supported use for localized chondral defects when other treatments have not been successful. The most recent clinical input was generally supportive of the use of ACI for large patellar lesions, although there was a range in the degree of support. Reviewers indicated
Autologous Chondrocyte Implantation

that outcomes were improved when realignment procedures were performed concurrently with ACI of the patella, and that success rates were lower when using ACI after a prior microfracture. A majority of reviewers recommended that a prior surgical procedure not be required for lesions greater than 4 centimeters.

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 and patella caused by acute or repetitive trauma when all of the following criteria are met:
1. Adolescent patients are skeletally mature with documented closure of growth plates (e.g., 15 years or older)
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 of the patella or the weight bearing surface of the femoral condyles or trochlea at least 1.5 cm² in size
4. Documentation of 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

III. Limitations
A. For smaller lesions (e.g., smaller than 4 cm²), 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. In addition, meniscal allograft transplantation may be performed in combination, either concurrently or sequentially, with ACI.
C. The charges for the culturing component of the procedure are submitted as part of the hospital bill.
D. The entire ACI procedure consists of 4 steps: (1) 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) 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.
E. ACI for all other joints, including the 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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<th>CPT Codes</th>
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<tr>
<td>27412</td>
<td>Autologous chondrocyte implantation, knee</td>
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<tr>
<td>29870</td>
<td>Arthroscopic harvesting of chondrocytes from the knee</td>
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<td>S2112</td>
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<td>Autologous cultured chondrocytes, implant</td>
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<th>ICD-9 PCS Codes</th>
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<td>80.16</td>
<td>Arthrotomy of the knee</td>
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<td>0SUC47Z, 0SUD47Z</td>
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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
Autologous Chondrocyte Implantation

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 language will control. There are any conflicts between these guidelines and the contract language, benefit determinations are subject to applicable member contract language. To the extent intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

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


