Autologous Chondrocyte Implantation

Clinical Coverage Criteria

Overview

An Autologous Chondrocyte Implantation (ACI) involves tissue engineering which creates a graft from a patient's own cartilage cells to repair defects in the articular cartilage. This involves collection and in-vitro expansion of articular cartilage cells which are implanted into the defected area in an attempt to improve the quality of the cartilage repair.

ACI for repair of focal cartilage defects of the knee involving injection of cultured chondrocytes under a periosteal flap is often referred to as first generation ACI. ACI requires two separate procedures. During the initial procedure, the patient's own chondrocytes are removed arthroscopically from a non-load-bearing area, either the intercondylar notch or the superior ridge of the medial or lateral femoral chondyles. The cells that are harvested are grown in vitro for approximately six weeks or until the population reaches 10-12 million cells. After this cell proliferation period, the patient undergoes a second procedure (typically, an arthrotomy under general anesthesia) in which the damaged cartilage is removed and the cultured chondrocytes are surgically injected under a periosteal flap, which has been sutured over the affected area. The implanted chondrocytes then integrate with surrounding tissue under the flap with the goal of generating hyaline-like cartilage. The primary advantage of ACI is the development of hyaline-like cartilage rather than fibrocartilage in the defect, presumably leading to better long-term outcomes.

There are several operative treatments available to treat focal cartilage defects. There are relative advantages and disadvantages to each technique. Procedures are classified by their relative ability to promote and restore the damaged articular surface. Considering size of the defect alone is insufficient to guide treatment due to overlapping indications for many of the available treatment options. In addition to lesion size, assessing the patient's current and desired activity level, symptom intensity, and response to previous treatment is helpful to compartmentalize treatment options. Operative treatment options for cartilage defects can be broadly categorized as follows:

1. Arthroscopic lavage and/or debridement
2. Marrow stimulating techniques (microfracture, subchondral drilling, and abrasion arthroplasty)
3. Osteochondral autograft (Mosaicplasty, OATS) or allograft
4. Cell-based replacement (e.g., autologous chondrocyte implantation)
5. Knee replacement

Diagnostic imaging is required to diagnose articular cartilage defects and should begin with a standard weight-bearing, anteroposterior (AP) radiograph of both knees in full extension, a non-weight-bearing 45-degree flexion lateral view and an axial view of the patellofemoral joint. Additionally, a 45-degree flexion weight-bearing posteroanterior (PA) radiograph can help identify subtle joint-space narrowing that traditional extension views may fail to uncover. Special studies such as a long-cassette mechanical axis view

or a magnetic resonance imaging (MRI) evaluation should be done as needed. If joint-space narrowing is present on the 45-degree flexion weight-bearing PA radiograph, an MRI is rarely necessary. Generally, MRI examination should be reserved for difficult cases in which the diagnosis remains unknown, especially in the setting of completely normal radiographs. The greatest strength of the MRI is its ability to evaluate the subchondral bone (Eg. osteochondral fractures, osteonecrosis, and osteochondritis dissecans).

X-rays with arthroscopic assessment are the gold standard for determining whether a symptomatic patient is a candidate for ACI. Arthroscopic assessment of the joint for possible ACI should include a careful and systematic evaluation of the articular surfaces with an arthroscopic probe to determine the size of the defect and the quality of the cartilage surrounding the defect. The opposing articular surface must be probed throughout to ensure that the meniscus is intact, the articular surface is healthy, and any chondromalacia is not greater than superficial fissuring.

Policy

Fallon Health requires Prior Authorization for Autologous Chondrocyte Implantation (ACI).

Fallon Health covers autologous chondrocyte implantation when documentation (i.e., reports of standing X-rays, arthroscopy results, operative notes, and medical records) addressing all of the following medical necessity criteria is submitted:

1. The plan member is skeletally mature and under 55 years of age there is insufficient evidence on the safety or efficacy of ACI in children and skeletally immature adolescents. Knee arthroplasty is the primary operative treatment for adults 55 years of age and older.
2. The plan member has no known history of hypersensitivity to gentamicin, other aminoglycosides or materials of bovine origin.
3. The plan members' body mass index (BMI) is less than or equal to 30.
4. The plan member is nicotine free prior to ACI.
5. The plan member has persistent symptoms (pain, catching, locking and/or swelling) with reduction in ADLs, which have failed to respond to at least six months of documented non-operative treatment. (Nonoperative treatment options for focal cartilage defects may include observation, weight loss, unloading braces, medications, corticosteroid injections, and viscosupplementation.)
6. The plan member has a single, focal cartilage defect located on the medial or lateral femoral condyle or trochlea. ACI is not covered for multiple defects or any defect that involves patellar cartilage.
7. The defect is caused by acute or repetitive trauma. Acute trauma includes falls, contact sports, and other sources of impact. Repetitive trauma includes overuse. ACI is not covered when the defect is due to osteochondritis dissecans.
8. The cartilage defect is full-thickness (modified Outerbridge grade III or IV, see below), and measures between 2 and 10 cm2 in area after debridement to healthy cartilage.
    - Arthroscopic debridement is recommended for defects < 1 cm2
    - A marrow stimulation technique (abrasion, drilling or microfracture) or osteochondral autograft is recommended and for defects 1 – 2 cm2

- Osteochondral allograft is recommended for defects greater than 10 cm2

9. In cases where the depth of the defect exceeds 8 – 10 mm, bone grafting is planned either at the time of the biopsy, as a separate procedure, or at the time of implantation of the cultured chondrocytes.
10. The plan member has failed a prior surgical repair procedure (e.g., arthroscopic debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft).
11. The plan member has intact, fully functional menisci and ligaments, normal alignment and normal joint space. The following conditions should be assessed and treated prior to or concurrent with implantation:
    - Unstable meniscus tears should be repaired or resected.
    - If the patient has had a total meniscectomy, absent meniscus should be reconstructed.
    - Instability of the knee may adversely affect the success of the procedure and should be corrected. The anterior and posterior cruciate ligaments should be free of laxity as well as stable and intact. It is recommended that cruciate deficiencies be corrected.
    - Abnormal weight-distribution within the joint may adversely affect the success of the procedure and should be corrected. The tibial/femoral joint should be properly aligned. When treating trochlear defects, abnormal patellar mechanics should be assessed and corrected.
12. The plan member does not have an arthritic condition that appears on standing X-rays as joint space narrowing, osteophytes, or changes in the underlying bone. The plan member does not have an inflammatory (rheumatoid or other) or degenerative (osteoarthritis) arthritis.
13. The plan member has no known malignancies in the area of the cartilage biopsy or implant. The potential exists for in vitro expansion and subsequent implantation of malignant or dysplastic cells present in biopsy tissue. In addition, implantation of normal autologous chondrocytes could theoretically stimulate growth of malignant cells in the area of the implant.
14. The plan member has been thoroughly educated about the procedure and rehabilitation. The plan member has realistic expectations and agrees to comply with the rehabilitation protocol which may include a period of non-weight-bearing followed by limited weight-bearing for many weeks.

    Classification of articular cartilage defects – there are several different classification systems of the description of articular cartilage defects, each has certain limitations and deficiencies which can lead to confusion. One frequently used classification system is the Modified Outerbridge

Classification System:

- Grade 0: normal cartilage
- Grade I: cartilage with softening and swelling
- Grade II: a partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter (<50% loss of cartilage thickness)
- Grade III: fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm (>50% loss of cartilage thickness)
- Grade IV, exposed subchondral bone

Exclusions

- ACI in pediatric patients (the safety and efficacy of Chondrocytes in pediatric patients has not been established) Unless considered skeletally mature.
- ACI in adults over age 65 (the safety and efficacy of Chondrocytes in adults over the age of 65 has not been established).
- ACI for the treatment of articular cartilage defects on the patella (the safety and efficacy of Chondrocytes for the treatment of patellar cartilage defects has not been established).
- ACI for the treatment of articular cartilage defects on the talus (the safety and efficacy of talar cartilage defects has not been established).

Codes

Code type	Code	Description
CPT	27412	Autologous chondrocyte implantation, knee
HCPCS	J7330	Autologous cultured chondrocytes, implant
	S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

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Policy History

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