

**Policy terminated because Medicaid covers codes in the same manner as
Health Choice.**

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1.0 Description of the Procedure, Product, or Service

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 recipient'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 autologous chondrocyte implantation (ACI) attempt to regenerate hyaline-like cartilage and thereby restore durable function.

With autologous chondrocyte implantation, a region of healthy articular cartilage is identified and biopsied through arthroscopy. The tissue is sent to a facility licensed by the 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 recipient 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.

The culturing of chondrocytes is considered by the FDA to fall into the category of manipulated autologous structural cells, which are subject to a biologic licensing requirement. At the present time, only Carticell (Genzyme) has received FDA approval for the culturing of chondrocytes through a biologics license. In 1997, Carticel 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...." The labeled indication was revised in October 1999 to read as follows:

"Carticel is indicated for the repair of symptomatic cartilaginous defects of the femoral condyle (medial, lateral or trochlear), caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure." Thus the revised labeling suggests a more restricted use of autologous chondrocyte, i.e., as a second-line therapy after failure of initial arthroscopic or surgical repair.

"Carticel is not indicated for the treatment of cartilage damage associated with osteoarthritis. Carticel should only be used in conjunction with debridement, placement of a periosteal flap and rehabilitation. The independent contributions of the autologous cultured chondrocytes and other components of the therapy to outcome are unknown. Data regarding functional outcomes beyond 3 years of autologous cultured chondrocyte treatment are limited."

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

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 recipients who have had an inadequate response to a prior surgical procedure, when **ALL** of the following criteria are met:

- a. The recipient is skeletally mature and not considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., age greater than 15 and less than 55);
- b. Focal, full thickness (grade III or IV) uni-polar lesions on the weight bearing surface of the femoral condyles or trochlea at least 1.5 cm² in size;
- c. 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;
- d. Normal knee biomechanics, or alignment and stability achieved concurrently with autologous chondrocyte implantation; **AND**
- e. Absence of meniscal pathology.

3.3 Policy Guidelines

- a. If debridement is the only prior surgical treatment, consideration should be given to marrow stimulating techniques before autologous chondrocyte implantation is performed. The average defect size reported in the literature is about 5cm²; many studies treated lesions as large as 15cm².
- b. Severe obesity (body mass index > 35 kg/m²), may affect outcomes due to the increased stress on weight-bearing surfaces of the joint.

- c. Misalignment and instability of the joint are contraindications, therefore, additional procedures, such as repair of ligaments or tendons or creation of an osteotomy for realignment of the joint, may be performed at the same time.
- d. Although long-term studies are lacking, evidence indicates that ACI can improve symptoms in some recipients with lesions of the articular cartilage of the knee who have failed prior surgical treatment. These recipients, 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, combined with contextual factors, it is concluded that ACI may be considered an option for disabling full thickness chondral lesions of the knee caused by acute or repetitive trauma, in recipients who have had an inadequate response to a prior marrow stimulation procedure. 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 joints other than the knee.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Autologous chondrocyte implantation is not covered for all other indications including:

- a. patellar and talar lesions;
- b. recipients who have an infection at any of the operative sites;
- c. osteoarthritis;
- d. inflammatory diseases of the joint;
- e. recipients with a known history of an allergy to the antibiotic gentamicin;
- f. recipients with sensitivities to materials of a bovine origin;
- g. recipients with an unstable knee;
- h. recipients who have abnormal distribution of weight within the joint;
- i. recipients who have had previous cancer in the bones, cartilage, fat, or muscle of the treated limb;
- j. kissing lesions; and
- k. total meniscectomy.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for Autologous Chondrocyte Implantation.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.
February 29, 2012	Throughout	Policy Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes				
29870	29871	29873	29874	29875
29876	29877	29879	29880	29881
29882	29883	29884	29885	29886
29887	27334	27335	27403	
27412				

HCPCS Code(s)
J7330
S2112

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital.

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.