Definition

Autologous cultured chondrocyte implantation (ACI) with Carticel® is a 2-stage procedure that is performed for the treatment of patients with symptomatic focal chondral lesions of the femoral condyle (medial, lateral or trochlear aspects) of the knee joint. The goal of ACI is to restore the articular surface and regenerate hyaline cartilage without compromising the integrity of healthy tissue or the subchondral bone.

The first stage of the procedure requires obtaining a small cartilage biopsy arthroscopically from a minor load-bearing area of the knee. The patient’s chondrocytes are isolated from the cartilage matrix in the laboratory. The cells are expanded in culture to a population of approximately 12 million viable cells (a 3- to 4-week process), and are then placed in suspension and returned for implantation. The second stage requires the patient to return for arthrotomy to complete debridement, periosteal patch and implantation of the cultured chondrocytes.

Following the second stage surgical procedure, a carefully monitored and controlled physical therapy program is instituted to continue over the following months. Low-impact activity may be resumed as early as 6 months after treatment. High-impact activity should be restricted for at least 12 months, as this will allow the repair tissue to complete its maturation.

Guideline

Members are eligible for ACI coverage for the repair of symptomatic, cartilaginous defects of the femoral condyle (medial, lateral or trochlear aspects) caused by acute or repetitive trauma with an inadequate response to a prior arthroscopic or other surgical repair procedure.

All of the following criteria must be met:
2. Presence of Grade III or Grade IV full thickness articular cartilage loss on a weight-bearing surface of the femoral condyle (medial, lateral or trochlear aspects).
3. The lesion must be symptomatic, defined as lesion-related pain; swelling or catching/locking that limits activities of daily living.
4. The focal chondral defect size should be between 1 cm and 10 cm.
5. The knee must be stable and aligned (a corrective procedure in combination with or prior to ACI may be necessary to ensure stability, alignment and normal weight distribution within the joint).
6. Prior to the procedure, there must be an expectation that the member will be able to fully participate in a prescribed post-op rehabilitation program necessary to insure optimal outcome.

Note: Members can develop a new injury and another cartilage defect in the same knee. A subsequent or second procedure for a different defect of the same knee may be deemed medically necessary only if it is performed at least 6 months after the prior or initial procedure on that knee.

Documentation
All of the following must be documented and made available to the plan upon request:

1. Signs and symptoms limiting activities of daily living (pain, swelling, locking, crepitus, catching, giving-way, etc.).
2. Dates and outcomes of all previous surgical procedures on the knee (chondroplasty, drilling, microfracture, debridement, abrasion, etc.).
3. Pre-operative confirmation that the knee is stable and aligned with normal or optimal weight distribution within the joint.
4. The location, dimensions, grade and depth of the identified focal chondral lesion, the condition of the surrounding articular cartilage.

Documentation must support that prior to the procedure there was an expectation that the member would be able to fully participate in the post-op rehabilitation program necessary to insure optimal outcome.

Limitations/Exclusions
1. ACI is not considered medically necessary for the following investigational indications:
   - Kissing lesions (includes degeneration or disease on the femoral and tibial aspect of the joint).
   - Patella.
   - Patellofemoral disorders.
   - In joints other than the knee.

2. Repeat ACI for the same lesion is not considered medically necessary, as it has not been sufficiently studied.

3. ACI is not considered reasonable and medically necessary in the following circumstances:
- As initial or first line surgical therapy.
- In a member who has had a previous total meniscectomy.
- In a member with a known history of anaphylaxis to gentamicin or sensitivities to materials of bovine origin.
- In a member with infection at any of the proposed operative sites.
- In a member with a cartilaginous defect associated with osteoarthritis or inflammatory diseases or where an osteoarthritic or inflammatory process significantly and adversely affects the quality of the peri-lesional cartilage.
- > 55 years of age.

**Applicable Procedure Codes**

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J7330</td>
<td>Autologous cultured chondrocytes, implant</td>
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<tr>
<td>S2112</td>
<td>Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)</td>
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<td>27412</td>
<td>Autologous chondrocyte implantation, knee</td>
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**Applicable ICD-10 Codes**

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<tr>
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<th>Description</th>
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<tr>
<td>M24.10</td>
<td>Other articular cartilage disorders, unspecified site</td>
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<td>M25.861</td>
<td>Other specified joint disorders, right knee</td>
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<td>M25.862</td>
<td>Other specified joint disorders, left knee</td>
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<td>M25.869</td>
<td>Other specified joint disorders, unspecified knee</td>
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<td>M94.8X8</td>
<td>Other specified disorders of cartilage, other site</td>
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<tr>
<td>M94.9</td>
<td>Disorder of cartilage, unspecified</td>
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**References**


Specialty-matched clinical peer review.