Autologous Chondrocyte Implantation

Definition

MACI® (autologous cultured chondrocytes on porcine collagen membrane) — an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. MACI is a cellular sheet that consists of autologous chondrocytes seeded on a 3 x 5 cm, resorbable porcine Type I/III collagen membrane. The active ingredients of MACI are the autologous cultured chondrocytes and porcine Type I/III collagen.

Guideline

Autologous chondrocyte implantation (ACI) is considered medically necessary for the repair of symptomatic, cartilaginous defects of the knee caused by acute or repetitive trauma when all of the following criteria are met:

1. **Age** 15–55 years of age
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. Lesion is symptomatic (defined as lesion-related pain; swelling or catching/locking that limits activities of daily living)
4. The focal chondral defect size is between 1–10 cm
5. Inadequate response to prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty or osteochondral allograft/autograft)
6. 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)
7. 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 indications due to insufficient evidence of therapeutic value:
   - Kissing lesions (includes degeneration or disease on the femoral and tibial aspect of the joint)
   - History of patellar/multiple defects
   - 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 (Note: presence of an unstable or torn meniscus requires partial resection, repair or replacement prior to or concurrent with MACI implantation. MACI is not recommended in patients with a 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 (Clinical trials of MACI did not include subjects over the age of 55)
Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>Aug. 14, 2020</td>
<td>Removed &quot;Patellofemoral disorders&quot; from the list of conditions for which ACI is not considered medically necessary, as it is already excluded under &quot;History of patellar/multiple defects.&quot;</td>
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<tr>
<td>Oct. 13, 2017</td>
<td>Replaced Carticel (removed from the market) with MACI</td>
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Applicable Procedure Codes

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

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


Specialty-matched clinical peer review.