

## Autologous Chondrocyte Implantation—Pre-authorization Checklist

The following checklist reflects the minimum requirements that the plan will need at the time of pre-authorization. Failure to include all of this information in the pre-authorization request or failure to make sure that all 'no' answers are fully addressed in the pre-authorization request will significantly increase the likelihood that the pre-authorization request will be denied or significantly delayed.

Function limiting pain (e.g., loss of knee function which interferes with the ability to carry out age appropriate ADL and/or demands of employment)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Presence of BOTH of the following on physical examination: <ul style="list-style-type: none"> <li>• A stable knee with intact or reconstructed ligaments</li> <li>• Normal tibial-femoral and/or patella-femoral alignment</li> <li>• A concurrent ligament stabilization or meniscal procedure at the time of ACI would be acceptable</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Failure of provider-directed non-surgical management for at least three (3) months in duration	<input type="checkbox"/> Yes <input type="checkbox"/> No
A full-thickness, single or multiple, distal femoral articular surface (i.e., medial condyle, lateral condyle, or trochlea) and/or patellar chondral defect of 1-10 cm <sup>2</sup> in size that has been identified during an MRI or CT arthrogram, or during an arthroscopy and classified by the Modified Outerbridge Scale as Grade III or Grade IV	<input type="checkbox"/> Yes <input type="checkbox"/> No
Minimal to absent osteoarthritis changes in the surrounding articular cartilage (Kellgren-Lawrence grade 2 or less)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Normal articular cartilage at the lesion border (contained lesion)	<input type="checkbox"/> Yes <input type="checkbox"/> No
BMI 35 or less	<input type="checkbox"/> Yes <input type="checkbox"/> No
Age 15-55 years	<input type="checkbox"/> Yes <input type="checkbox"/> No
Confirm absence of: <ul style="list-style-type: none"> <li>• Osteochondritis dissecans (OCD) lesion that requires bone grafting</li> <li>• Inflammatory arthritis or other systemic disease affecting the joints</li> <li>• Any knee joint surgery within six (6) months before screening excluding surgery to procure a biopsy or concomitant procedure to prepare the knee for MACI implant</li> <li>• Modified Outerbridge Grade III or IV defects on the tibia</li> <li>• Presence of Kellgren-Lawrence grade 3 or 4 osteoarthritic changes in the surrounding articular cartilage</li> <li>• Total meniscectomy, meniscal allograft, or bucket-handle tear or displaced tear requiring &gt; 50% removal of the meniscus in the target knee</li> <li>• Septic arthritis within one (1) year before screening</li> <li>• Known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin</li> <li>• Uncorrected congenital blood coagulation disorders</li> <li>• Cruciate ligament instability</li> <li>• Hybrid ACI performed with osteochondral autograft (OATS) is considered experimental and investigational</li> <li>• For femoral and patellar chondral lesions, a corresponding "kissing" lesion with a modified Outerbridge Scale of Grade III or IV of the distal femur (trochlea, condyles), patella, or tibia</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No

**All 'no' answers must be fully addressed at time of pre-authorization.**

The reimbursement material contained in this guide represents our current (as of January 2024) understanding of the pre-authorization checklists reflected in various payer policies. Many of the topics covered in this guide are complex and all are subject to change beyond our control. Healthcare professionals are responsible for keeping current and complying with reimbursement-related rules and regulations. Nothing contained herein is intended, nor should it be construed as, to suggest a guarantee of coverage or reimbursement for any product or service. Check with the individual insurance provider regarding coverage. Providers should exercise independent clinical judgment when submitting claims to reflect accurately the services rendered to individual patients.