# Payors Without Formal Medical Policy Criteria

## Autologous Chondrocyte Implantation—Pre-authorization Checklist*

The following checklist reflects common payor requirements for MACI® (autologous cultured chondrocytes on porcine collagen membrane). 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.

**More restrictive plans may require additional documentation to demonstrate medical necessity. Best practice is to include these items.**

| | |
|---|---|
| Defect information should include:<br>• Treatment is for focal, full-thickness (Outerbridge Classification of Grade III or IV) lesions<br>**Documentation to consider:** if bipolar lesions, why MACI is the only appropriate treatment and if concurrent processes will correct maltracking or cause of bipolar lesions<br>• Location of the defect is on the weight bearing surface of the patella, trochlear groove, or the femoral condyle (medial, lateral)<br>• Size of the defect is at least 1.5 $cm^2$ | ☐ Yes ☐ No |
| Patient Information should include:<br>• BMI is less than or equal to 35<br>• Patient aged 15-55 years old<br>- If under 18 years old, documented closure of growth plates<br>• Function-limiting pain<br>**Documentation to consider:** function-limiting pain of ≥ 3/10 and interferes with knee function in 2 areas of activities of daily living<br>• Capable of cooperating with post-operative weight bearing restrictions and completion of post-operative rehabilitation.<br>• Failure of previous treatment<br>- Inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft<br>**Documentation to consider:** failure of provider-directed, non-surgical/conservative treatment for at least three (3) months including physical therapy or compliance with a physician directed HEP | ☐ Yes ☐ No |
| Physical examination findings should include the following:<br>• A stable knee with intact or reconstructed ligaments (ACL or PCL) OR ligamentous issues that will be addressed concomitantly<br>• Normal tibial-femoral and/or patella-femoral alignment OR will be addressed concomitantly<br>• 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 | ☐ Yes ☐ No |
| Confirm absence of:<br>• Moderate-severe OA of the knee, generalized tibial chondromalacia, and inflammatory arthritis or other systemic disease affecting the joints<br>• Any indication not listed above.<br>• Treatment of joints other than the knee (e.g., shoulder, hip, tibia, talus, glenohumeral)<br>• History of total meniscectomy (≥50% meniscus remains intact)<br>• A cartilaginous defect (related to osteoarthritis, rheumatoid arthritis or inflammatory diseases) or where an osteoarthritic or inflammatory process unfavorably affects peri-lesional cartilage quality<br>• Osteochondritis dissecans<br>• Contraindications<br>- Known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin.<br>- Severe osteoarthritis of the knee, inflammatory arthritis, inflammatory joint disease<br>- Presence of cancer/malignancy in area of treatment<br>- Uncorrected congenital blood coagulation disorders.<br>- Prior knee surgery in the past 6 months, excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant.<br>- Individual is unable to follow a physician-prescribed post-surgical rehabilitation program. | ☐ Yes ☐ No |

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