



**MACI**® (autologous cultured chondrocytes on porcine collagen membrane)

## Peer-to-Peer Review Guidance

Call us at **877-872-4643** with any questions

**Important note:** The following are only guidelines. Each discussion should be based on your evaluation and conclusions of MACI's appropriateness for the individual patient.

### Pre call recommendations

1. **Request an orthopedic specialist for the Peer-to-Peer review**
2. **Prepare MACI evidence specific to the denial** (*MyCartilage Care may assist by providing literature*)
3. **Schedule the call immediately after the denial notification** (*Timeframe for the P2P may be limited following the denial*)
4. **The payor may consider a missed call to be a failed first level of appeal and uphold the denial**

### On the call

1. **Conduct the Peer-to-Peer call personally** (*Example: I have been Mr. Smith's treating physician for 3 years*)
2. **Provide a brief description of your background** (*Ask for the credentials of the Medical Director to best frame the conversation around their level of expertise in orthopedics*)
3. **Ask if they have the authority to overrule a denial** (*If the person on the call does not have such authority, request a call with an orthopedic surgeon experienced in cartilage surgery or the Medical Director*)
4. **Highlight the individual patient situation and medical necessity rationale** (*Example: Mr. Smith has been symptomatic for over a year and has significantly altered his activities of daily living to compensate for the pain*)
5. **(If applicable) detail previous failed therapies** (*Example: To date patient has not responded well to non-surgical treatments or conservative surgical treatments including: Anti-inflammatory and other oral medications, activity modification, physical therapy, and bracing*)
6. **Explain why you believe MACI is right for the patient and other therapies are not ideal** (*Example: Due to lesion size, I do not feel microfracture is a good choice for this patient,*

*especially considering the body of literature indicating microfracture in the patellafemoral joint is less than ideal. Also, I am concerned microfracture could disrupt the subchondral cortical bone and decrease the efficacy of the autologous chondrocyte Implantation as recent literature has concluded.)*

#### 7. Clarify the risks of delaying surgery (if any)

- **Physical concerns** (*Example: With continued delay, Mr. Smith faces the risk of increased deterioration and may no longer be a candidate for the proposed surgical repair*)
- **Health expenditures** (*Example: Without this treatment, medical costs for Mr. Smith will continue to increase along with the need for additional surgeries and various related medical services*)
- **Secondary morbidity** (*Example: This surgery may allow Mr. Smith to avoid treatment for other potentially related conditions*)

### Ending the call

1. **Make clear the insurer's approval to overturn the denial is the patient's only point of access to obtain the medically necessary treatment**
2. **Repeat the condition's effect on the patient's quality of life** (*Example: Mr. Smith's quality of life will continue to decline. I believe it is important to support the patient's ability to return to an active lifestyle*)

Politely request confirmation of the overturned denial



## Take the first step

toward helping your patients reach  
their cartilage treatment goals

[MyCartilageCare.com/approval](http://MyCartilageCare.com/approval) | 1-877-872-4643



autologous cultured  
chondrocytes  
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### INDICATION

MACI<sup>®</sup> (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product that is indicated for the repair of single or multiple symptomatic, full-thickness cartilage defects of the adult knee, with or without bone involvement.

MACI is intended for autologous use and must only be administered to the patient for whom it was manufactured. The implantation of MACI is to be performed via an arthrotomy to the knee joint under sterile conditions.

The amount of MACI administered is dependent upon the size (surface in cm<sup>2</sup>) of the cartilage defect. The implantation membrane is trimmed by the treating surgeon to the size and shape of the defect, to ensure the damaged area is completely covered, and implanted cell-side down.

#### Limitations of Use

Effectiveness of MACI in joints other than the knee has not been established.

Safety and effectiveness of MACI in patients over the age of 55 years have not been established.

### IMPORTANT SAFETY INFORMATION

MACI is contraindicated in patients with a known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin. MACI is also contraindicated for patients with severe osteoarthritis of the knee, inflammatory arthritis, inflammatory joint disease, or uncorrected congenital blood coagulation disorders. MACI is also not indicated for use in patients who have undergone 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.

MACI is contraindicated in patients who are unable to follow a physician-prescribed post-surgical rehabilitation program.

The safety of MACI in patients with malignancy in the area of cartilage biopsy or implant is unknown. Expansion of present malignant or dysplastic cells during the culturing process or implantation is possible.

Patients undergoing procedures associated with MACI are not routinely tested for transmissible infectious diseases. A cartilage biopsy and MACI implant may carry the risk of transmitting infectious diseases to healthcare providers handling the tissue. Universal precautions should be employed when handling the biopsy samples and the MACI product.

Final sterility test results are not available at the time of shipping. In the case of positive sterility results, health care provider(s) will be contacted.

To create a favorable environment for healing, concomitant pathologies that include meniscal pathology, cruciate ligament instability and joint misalignment, must be addressed prior to or concurrent with the implantation of MACI.

Local treatment guidelines regarding the use of thromboprophylaxis and antibiotic prophylaxis around orthopaedic surgery should be followed. Use in patients with local inflammations or active infections in the bone, joint, and surrounding soft tissue should be temporarily deferred until documented recovery.

The MACI implant is not recommended during pregnancy. For implantations post-pregnancy, the safety of breast feeding to infant has not been determined.

Use of MACI in pediatric patients (younger than 18 years of age) or patients over 65 years of age has not been established.

The most frequently occurring adverse reactions reported for MACI (≥5%) were arthralgia, tendonitis, back pain, joint swelling, and joint effusion.

Serious adverse reactions reported for MACI were arthralgia, cartilage injury, meniscus injury, treatment failure, and osteoarthritis.

