maci autologous cultured chondrocytes on porcine collagen membrane

MyCartilage Care®

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

Letter of Medical Necessity Guidance

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

A Letter of Medical Necessity accomplishes two tasks: First it provides a clear and concise snapshot of the patient's background and condition. Next it presents the proposed treatment as reasonable and necessary within evidence-based standards of care. Each Letter of Medical Necessity should be based on the specific requirements of the patient's insurance carrier.

State the patient's background and condition	• *Medical history* • *Failed therapies* • *Age and BMI appropriate*
Explain and justify your clinical decision making process	• *Measure medical criteria against medical policy or FDA criteria* • *Explain why alternative treatment options may be less desirable based on your observations of the patient* • *Reference literature in medical decision rationale for each off-policy defect*
Outline risk if treatment is not provided or delayed	• *Physical issues that may remain unresolved* • *Increased future health expenditures* • *Potential risks of secondary morbidity* • *Impact on patient quality of life*

Conclude by repeating your frank perspective.
Please review the sample Letter of Medical Necessity provided.

Letter of Medical Necessity Example

[Date]

Payor Name: [Name of Insurer]
Policy Number: [Insurance ID #]
Patient Name: [Name]
DOB: [Date]
Service: [CPT 27412 (Repair, Revision, and/or Reconstruction Procedures on the Femur (Thigh Region) and Knee Joint.) with J7330 (Autologous cultured chondrocytes, implant) xxx revert xxxx]

Dear Medical Director [or Name, if known];

I am writing on behalf of my patient, [Patient Name], to request prior authorization for treatment with MACI (autologous cultured chondrocytes on porcine collagen membrane). Please review below for [Patient Name]'s individual consideration based on medical history, diagnosis, and a statement summarizing my treatment plan. Considering the circumstances surrounding [Patient Name], my professional opinion is that MACI surgery is the best treatment option.

[Patient's Name] is a [age]-year old [male/female] who has been symptomatic for [number] years with [failed surgical and non-surgical intervention(s)]. [Patient's Name's] daily responsibilities require [physical demands of daily responsibilities]. Due to ongoing [symptoms], [Patient Name] is unable to perform [his/her] daily activities and [his/her] quality of life is severely impacted. [Patient Name] has a BMI of [number] and expresses motivation to comply with post-operative weight-bearing restrictions and rehabilitation.

Patient's Clinical History

- [He/She] underwent [describe procedure(s) to date]
- [Diagnosis]
- [Past treatments]
- [Extenuating circumstances precluding alternatives to MACI procedure]
- [Risks of delaying procedure]

Literature References
In reviewing peer-reviewed literature, [discuss supporting literature for MACI and Patient's specific case if not meeting standard criteria].

Summary
In summary, please consider approval for the use and subsequent payment for MACI on [Patient Name]'s behalf. Please refer to the enclosed Prescribing Information and other supporting documents for MACI. If you have any further questions regarding this matter, please do not hesitate to call me at [MD phone number]. Thank you for your prompt attention to this matter. I look forward to a favorable response.

Thank you for your time and consideration.

Sincerely,

[Physician's name and credentials]

Enclosures: [suggested enclosures:]
• MACI Prescribing Information
• Journal articles, clinical practice guidelines, and other supporting documentation

For assistance with providing applicable medical references, call MyCartilageCare® at 877-872-4643

MyCartilage Care®

Take the first step

toward helping your patients reach their cartilage treatment goals

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maci®

autologous cultured chondrocytes on porcine collagen membrane

INDICATION

MACI® (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^2) 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.

https://www.maci.com/pdf/maci-full-prescribing-information.pdf

VERICEL

Please see Full Prescribing Information, or visit MACI.com