**Creating a Letter of Medical Necessity (LOMN)**

The following template is designed to assist in capturing key elements payor plans commonly use to make their decision when considering an ACI approval.

Using this letter:

* Letters of Medical Necessity should be on the physician’s letterhead
* The letter should be customized for the patient’s insurance provider. Check the provider’s medical policy to determine the rationale for exclusion.
* Replace all [bracketed] text with the appropriate, patient-specific information and delete any text that does not apply specifically to the patient for whom the letter is being written
* Be sure to enclose a list of documents supporting your rationale of therapy

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

THE SAMPLE LETTER OF MEDICAL NECESSITY IS NOT INTENDED TO BE USED VERBATIM. UTILIZING THIS TEMPLATE DOES NOT GAURANTEE APPROVAL. HEALTHCARE PROVIDERS SHOULD MAKE THE ULTIMATE DETERMINATION AS TO WHEN TO USE A SPECIFIC PRODUCT BASED ON CLINICAL APPROPRIATENESS FOR A PARTICULAR PATIENT. ALL NOTES MUST ACCURATELY REFLECT THE FACTS UNIQUE TO INDIVIDUAL APPLICATIONS.

**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 cm²) 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 orthopedic 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.

Please see [Full Prescribing Information](http://www.maci.com/pdf/Final-MACI-PI-FINAL.pdf) for more information

MACI®, MyCartilageCare®, Vericel®, and the Vericel logo are registered trademarks of Vericel Corporation.

©2022 Vericel Corporation. All rights reserved. PP.US.MAC.0479 v2.0

[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