maci autologous cultured chondrocytes on porcine collagen membrane

MyCartilage Care®

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

Dictation Roadmap

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

Insurance authorization of MACI is most likely when the prescribing physician's dictation addresses all of the insurer's specific medical policy criteria for ACI treatment.

To see provider policies click here and select the patient provider from the list.

Note unique patient descriptors as related to insurer criteria *(where applicable)*

Age

- *"The patient is skeletally mature with documented closure of growth plates."*
- *"The patient is too young for a knee replacement."*

BMI >35

- *"BMI due to high muscle mass."*
- *"The patient is on an alternative weight loss program as injury has limited the ability to exercise."*

Symptoms unique to the case

- *"The patient's disabling knee pain and swelling are limiting the ability to perform functional activities."*
- *"The patient is unable to participate in physical therapy requirement due to intractable pain."*

Clarify your clinical findings

Note if the overall condition of the knee and the treatment plan for concomitant conditions

- *"The knee is stable and intact, with fully functional menisci and ligaments, has normal joint space, and is in good alignment."*
- *"Alignment correction will be performed concomitantly with MACI to achieve knee stability."*

Describe the lesion, location and size

- *"The 1.5 cm x 1.5 cm full-thickness grade III lesion is isolated on the weight bearing surface of the femoral condyle."*
- *"The lesion is well contained with normal surrounding cartilage."*

Explain your assessment and plan

If applicable, explain the patient's functional limitations:

- *"The patient experiences loss of knee function that interferes with the ability to perform activities of daily living (i.e., walking, stair climbing) and/or employment."*
- *"The patient has experienced disabling localized pain of at least a 3/10 intensity for at least 3 months."*

If applicable, describe the failure of previous treatments

- *"After three months, the patient has failed to respond to:*
  - non-operative treatments (NSAIDs, injections, etc.);
  - activity modification; and
  - physical therapy OR physician directed home exercise program."
- *"The patient had an inadequate response to debridement."*
- *"The patient wishes to undergo MACI treatment for her cartilage damage due to continued pain and limitation of her functional activity."*

If applicable, note that the patient has none of the following:

- *Osteoarthritis or arthritis in joint*
- *Kissing lesions*
- *Current infections*
- *Allergy to gentamicin or materials of bovine origin*
- *History of cancer in the bones, cartilage, fat or muscle of the affected limb*

Indicate the patient has provided consent for this treatment

- *"The patient understands the risk and potential benefits associated with the ACI procedure and has realistic expectations."*
- *"The patient is willing to comply with weight bearing restrictions and rehabilitation requirements following the ACI procedure."*

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.

VERICEL®

Please see Full Prescribing Information, or visit MACI.com