MyCartilage Care®

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

MACI® (autologous cultured chondrocytes on porcine collagen membrane)

Publications supporting treatment of patella lesions

Important note: *It may be important to cite literature to help provide justification when seeking a prior authorization approval for MACI treatment in the patella, as some payors are not familiar with the effectiveness of MACI for these cases. Each approval request should be based on your evaluation and conclusions of MACI's appropriateness for the individual patient.* **Below are examples of peer-reviewed publications demonstrating successful outcomes of Autologous Chondrocyte Implantation (ACI) in the patella.**

A study of combined ACI and AMZ resulted in significant improvements in symptoms and function in patients with isolated symptomatic patellar chondral defects

Gillogly SD, Arnold RM. Autologous chondrocyte implantation and anteromedialization for isolated patellar articular cartilage lesions: 5 to 11-year follow-up. *Am J Sports Med* 2014 Apr;42(4):912-20.

In a study of 52 patients who underwent ACI of the patellofemoral joint, significant improvement was demonstrated in KOOS Symptoms, KOOS Activities of Daily Living, KOOS Sport, Cincinnati, Tenger, and SF-12 Physicals

Pascual-Garrido C, Slabaugh MA, L'Heureux DR et al. Recommendations and treatment outcomes for patellofemoral articular cartilage defects with autologous chondrocyte implantation: prospective evaluation at average 4-year follow-up. *Am J Sports Med* 2009; 37 Suppl 1:33S-41S.

47 consecutive patients undergoing MACI in the patellofemoral joint, as well as each of the 4 procedural subgroups, demonstrated overall clinically and statistically significant improvements over time for all clinical scores reported

Ebert J, Fallon M, Smith A, Janes G, WoodD. Prospective clinical and radiologic evaluation of patellofemoral matrix-induced autologous chondrocyte implantation.. *Am J Sports Med* 2015 Jun 17;43(6):1362-72. Epub 2015 Mar 17.

Significant clinical improvement in 12 patients support the value of associating distal realignment and ACI in treating large, isolated, patellar cartilage lesions associated with patellofemoral malalignment

Gigante A, Enea D, Greco F. Distal realignment and patellar autologous chondrocyte implantation: mid-term results in a selected population. *Knee Surg Sports Traumatol Arthrosc* 2009;17:2–10.

A Comparison of clinical outcomes between patients undergoing isolated patellofemoral ACI and ACI combined with patellofemoral realignment showed significantly greater improvements in patients undergoing combined osteotomy and ACI

Trinh TQ, Harris J, Siston R, Flanigan D. Improved outcomes with combined autologous chondrocyte implantation and patellofemoral osteotomy versus isolated autologous chondrocyte implantation. *Arthroscopy* 2013 Mar 8;29(3):566-74.

MACI in the PF joint with concurrent correction of PF maltracking, if required, leads to similar clinical and radiological outcomes compared with MACI on the femoral condyles

Ebert JR, et al. *Am J Sports Med*. 2017 Dec;45(14):3243-3253. doi: 10.1177/0363546517724761. Epub 2017 Sep 14.

Autologous Chondrocyte implantation to isolated patella defects results in significant functional improvement at a minimum of 24 months, with results remaining durable at latest follow up of 15 years

von Keudall, et al. Autologous Chondrocyte Implantation to Isolated Patella Cartilage Defects. *Cartilage*. 2017 Apr;8(2):146-154.

The clinical support for MACI/ACI in the patella is substantial. The Blue Cross Blue Shield Association's Evidence Street reviewed 20 publications concluding the evidence is sufficient to determine the technology results in meaningful improvement in net health outcomes.

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