MyCartilage Care®

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

MACI® (autologous cultured chondrocytes on porcine collagen membrane)

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 are 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 will remain unresolved* • *Increased future health expenditures* • *Risks of secondary morbidity* • *Return to patient quality of life*

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

Letter of Medical Necessity
Example Page 1

April 30th, 2018

Payor Name: BlueCross BlueShield
Patient Name: John Doe
DOB: 10/10/99
Policy Number: 555-55555-555-6
Service: CPT 27412: Autologous Chondrocyte Implantation with J7330: Autologous Cultured Chondrocytes (MACI)

Dear Reviewing Authority,

I am writing on behalf of my patient John Doe to document my conclusion of the medical necessity for treatment with MACI (matrix autologous chondrocyte implantation) surgery for his patella cartilage defect and request *individual consideration* of his case. Please review the summary below and the attached supporting documentation.

Over the past year, John Doe has been working with me to alleviate pain in his right knee, which has progressively worsened. As a 19 year old college track and field athlete he was extremely active prior this injury and has since been unable to participate in sports or any recreation. Additionally, Mr. Doe struggles with activities of daily living such as negotiating stairs and general mobility within a college campus setting. To date, my patient has not responded well to surgical treatment and exhaustive nonsurgical treatments consisting of anti-inflammatory medication, activity modification, physical therapy and bracing. I previously performed a knee arthroscopy and chondroplasty of the right knee which confirmed a grade III cartilage defect of the patella with healthy borders measuring 1 x 2.25 cm. Mr. Doe has a BMI of 18, there is no concern of osteoarthritis, his knee is mechanically stable and aligned, and he has agreed to a rigorous post-surgical rehab protocol.

MACI has been FDA approved for the repair of symptomatic, single or multiple full-thickness cartilage defect of the knee with or without bone involvement. MACI is appropriate to use to treat <u>any</u> articulating surface in the knee, including the patella.

In addition to FDA labeling including patella use, there is support in scientific literature. In January 2018, Blue Cross and Blue Shield released their Evidence Street summary on Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions. The summary states *"Individuals with focal articular cartilage lesion(s) of the weightbearing surfaces of the femoral condyles, trochlea, <u>or patella</u> who are treated with autologous chondrocyte implantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome."* Patella is included as an appropriate area of use.

A long-term outcomes study with MRI data confirms the durability of autologous chondrocyte implantation tissue for the treatment of isolated patella defects after a mean of 7.3 years follow-up. Patients were satisfied with their results up to fifteen years postoperatively. ACI for patella defect management of Fulkerson type III (medial facet) and type IV (panpatellar) defects is the most effective and durable treatment option available and has optimal results when performed as the primary surgery. (von Keudell 2017)

Very recently, Ebert (2017) shows continued support for MACI use for patellar defects, with outcomes in the patella being comparable to those in the femoral condyles.

Letter of Medical Necessity
Example Page 2

Patients with articular cartilage injuries present a challenge for an orthopedic surgeon. These patients progress in disability due to the inherent nature of cartilage defects and may find activities of normal life increasingly difficult, if not impossible, to carry out. ACI is a treatment option that offers these patients a promising opportunity to biologically repair the hyaline cartilage and allow them to return to their previous levels of activity. Lesion location should not be a barrier to approval of MACI for necessary and appropriate care, especially given that the literature clearly and repeatedly shows that the efficacy of this intervention includes the patella.

Given my first-hand experience with long-term outcomes of using autologous cultured chondrocytes for cartilage defects about the knee, my professional recommendation is that MACI surgery is the best treatment option for Mr. Doe.

Sincerely,

Surgeon name, MD, credentials

References:

1. Comparison of 2-Year Outcomes in Patients Undergoing Tibiofemoral or Patellofemoral Matrix-Induced Autologous Chondrocyte Implantation. American Journal of Sports Medicine. 2017 December. Ebert JR, Schneider A, Fallon M, Wood DJ, Janes GC.
2. BlueCross BlueShield Association. Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions. Evidence Summary 2018. **Full text included**
3. Matrix-Associated Autologous Chondrocyte Implantation: A Clinical Follow-Up at 15 Years. Cartilage. 2016 October. Gille J, Behrens P, Schulz AP, Oheim R, Kienast B.
4. Autologous Chondrocyte Implantation (ACI) for Knee Cartilage Defects A Review of Indications, Technique, and Outcomes. The Journal of Bone and Joint Surgery Reviews 2018 February, Krill, M, Early,N, Everhart, J, Flanigan, D
5. Autologous Chondrocyte Implantation to Isolated Patella Cartilage Defects. Cartilage 2017 April, Arvind von Keudell, Roger Han, Tim Bryant, and Tom Minas.
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7. Prospective clinical and radiologic evaluation of patellofemoral matrix-induced autologous chondrocyte implantation. American Journal of Sports Medicine. 2015 June. Ebert JR, Fallon M, Smith A, Janes GC, Wood DJ.
8. Autologous chondrocyte implantation in the knee: mid-term to long-term results. Journal of Bone and Joint Surgery 2014. Nawaz SZ, Bentley G, Briggs TW, Carrington RW, Skinner JA, Gallagher KR, Dhinsa BS.
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10. Autologous chondrocyte implantation in the patella: a multicenter experience. American Journal of Sports Medicine. 2014 May. Gomoll AH, Gillogly SD, Cole BJ, Farr J, Arnold R, Hussey K, Minas T.
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12. The role of autologous chondrocyte implantation in the treatment of symptomatic chondromalacia patellae. International Orthopaedics. 2012 July. Macmull S, Jaiswal PK, Bentley G, Skinner JA, Carrington RW, Briggs TW.
13. Recommendations and treatment outcomes for patellofemoral articular cartilage defects with autologous chondrocyte implantation: prospective evaluation at average 4-year follow-up. American Journal of Sports Medicine. 2009 November. Pascual-Garrido C, Slabaugh MA, L'Heureux DR, Friel NA, Cole BJ.
14. Distal realignment and patellar autologous chondrocyte implantation: mid-term results in a selected population. Knee Surgery Sports Traumatology Arthroscopy. 2009 Januar. Gigante A, Enea D, Greco F, Bait C, Denti M, Schonhuber H, Volpi P.

MyCartilage Care®

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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