KAISER PERMANENTE® Mid-Atlantic States	**Matrix-Induced Autologous Chondrocyte Implantation (MACI) Procedure for Repair of Articular Cartilage of the Knee** **Medical Coverage Policy**

Utilization *ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- Medicare does not have a National Coverage Determination (NCD) for MACI. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time. For coverage guidelines, refer to the Kaiser Permanente Mid-Atlantic States Medical Policy titled: Matrix-Induced Autologous Chondrocyte Implantation (MACI) Procedure for Repair of Articular Cartilage of the Knee.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. Procedure: Matrix-Induced Autologous Chondrocyte Implantation (MACI) Procedure for Repair of Articular Cartilage of the Knee

II. Specialty: Orthopedic Surgery

III. Definition

MACI® (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold sheet consisting of autologous chondrocytes seeded on a 3 x 5 cm, resorbable porcine Type I/III collagen membrane. The matrix-induced autologous chondrocyte implantation (Vericel Corporation) was approved by Food and Drug Administration on December 13, 2016, through the Biologics License Application (BLA) process. MACI is indicated for the repair of single or multiple symptomatic, full thickness cartilage defects of the knee with or without bone involvement in adults. The active ingredients of MACI are autologous cultured chondrocytes and porcine-derived resorbable Type I/III collagen membrane in addition to animal-derived reagents.

IV. Clinical Indications for Referral

Matrix-Induced Autologous Chondrocyte Implantation (MACI) is medically necessary for the repair of symptomatic, full thickness articular cartilage (single or multiple) defects of the knee, with or without bone involvement for those who meet **ALL** of the following criteria:

A. The request is reviewed on a case-by-case basis and authorized by the Regional Orthopedic Service Chiefs, or their appointees given the very highly selective clinical indication for MACI procedure; AND

B. The patient meets ALL of the following requirements:
   1. Symptomatic cartilage lesion of the femoral condyle, patella, or trochlea;
   2. Patient skeletally mature, with documented closure of growth plates (age greater than 10 but less than 55 years of age) and not considered an appropriate candidate for total knee arthroplasty or

other reconstructive knee surgery;
3. Lesion is too large for marrow stimulation, such as ≥ 2 cm2;
4. Full thickness lesion with normal surrounding cartilage;
5. Unipolar: facing cartilage is normal, such as.no kissing lesion;
6. No malalignment, long leg weight bearing alignment, X-rays were done and reviewed, or osteotomy is planned
7. No instability, or ligament reconstruction planned;
8. Body mass index less than 35;
9. No more than 50% partial meniscectomy;
10. No systemic disease, e.g., gout or rheumatoid arthritis; *and*
11. Able and willing to follow post-operative protocol of six weeks limited weight bearing

V. Pre-surgical Assessment of Comorbidities

Assessment and treatment of the following conditions should be made prior to or concurrent with implantation of MACI to create an optimal environment for healing:

A. Local inflammation or active infection in the bone, joint, and surrounding soft tissue
The MACI procedure should be deferred until complete recovery.

B. **Cruciate ligament instability**
Both the anterior and posterior cruciate ligaments along the joints should be stable or undergo reconstruction prior to or concurrent with MACI implantation as excessive laxity may create excessive shear and rotational forces across the joint.

C. **Misalignment**
The patella tracking should be normalized, and tibio-femoral joint properly aligned with corrective osteotomy or similar corrective procedure prior to or concurrent with MACI implantation as varus or valgus misalignment of the tibio-femoral joint and abnormal patella tracking may abnormally load joint surfaces and jeopardize the implant.

D. **Meniscal pathology**
The presence of an unstable or torn meniscus requires partial resection, repair, or replacement prior to or concurrent with MACI implantation. MACI is not recommended in patients with a total meniscectomy.

VI. Limitation and Contraindication

A. Limitations

1. MACI is intended solely for autologous implantation;
2. The safety and effectiveness of MACI for repair of articular cartilage of the knee have not been established for pediatric patients nor those over the age of 55 years
3. MACI's effectiveness to repair joints other than the knee have not been established.

B. Contraindications

MACI is contraindicated with the following:

1. For all other conditions not listed in section IV of this policy.
2. Known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin;
3. Prior knee surgery (6 months), excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant;
4. History of total meniscectomy;
5. Inflammatory arthritis, inflammatory joint disease, or uncorrected congenital blood coagulation disorders;
6. Severe osteoarthritis of the knee (Kellgren-Lawrence grade 3 or 4); *and*
7. Inability to cooperate with a physician-prescribed post-surgical rehabilitation program; and
8. Any patient who is not nicotine-free for at least 6 months prior to surgery

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
12/16/2020	12/16/2020
12/15/2021	12/15/2021
12/28/2022	12/28/2022
11/28/2023	11/28/2023
11/21/2024	11/21/2024

*****The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.