PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	MACI (autologous cultured chondrocytes)
BENEFIT TYPE	Medical
STATUS	Prior authorization required

MACI (autologous cultured chondrocytes on porcine collagen membrane), approved by the FDA in 2016, is used for the repair of symptomatic cartilage damage of the knee. It is made up of autologous cells that are collected on biopsy, expanded and proliferated in culture, and seeded onto a collagen membrane that is implanted to the area of defect and absorbed back into the tissue. The amount of MACI applied depends on the size of the cartilage defect (cm^2). The membrane is trimmed by the surgeon to the size and shape of the defect. Implantation is performed via arthrotomy.

MACI (autologous cultured chondrocytes) will be considered for coverage when the following criteria are met:

Cartilage defect of the knee

For **initial** authorization:

1. Member is 15 (with closed growth plates) to 55 years of age; AND
2. Medication must be prescribed by or in consultation with an orthopedic surgeon or PM&R (physiatry) specialist; AND
3. Member has a BMI of 35 or less; AND
4. Member has a diagnosis of single or multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement; AND
5. The defect size is greater than 2 cm^2; AND
6. Member has tried and failed conservative therapy such as physical therapy or anti-inflammatory medications; AND
7. The knee has stable alignment with the meniscus intact and normal joint space (per X-ray); AND
8. Documentation that the implantation will be followed by an appropriate, physician-prescribed rehabilitation program to which the member is expected to adhere; AND
9. Member does NOT have any of the following:
   a) Hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin
   b) Severe osteoarthritis of the knee or degenerative joint disease
   c) Inflammatory arthritis, inflammatory joint disease, or uncorrected congenital blood coagulation disorders
   d) Knee surgery within the past 6 months (except to procure biopsy or to perform a concurrent procedure with MACI)
   e) Osteochondritis dissecans
10. **Dosage allowed/Quantity limit:** 1 procedure per defect per lifetime.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. MACI will not be re-authorized. If the request is for a new defect/injury that has not previously been treated with MACI, all initial criteria apply.

HAP CareSource considers MACI (autologous cultured chondrocytes) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/22/2021	New policy created for Maci.
05/24/2022	Annual review; no changes.
01/14/2025	Updated references. Removed disabling knee pain criterion; #4 already specifies that they are symptomatic. Removed duration from trial of conservative therapy.

References:

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3. Brittberg M, Recker D, Ilgenfritz J, Saris DBF; SUMMIT Extension Study Group. Matrix-Applied Characterized Autologous Cultured Chondrocytes Versus Microfracture: Five-Year Follow-up of a Prospective Randomized Trial. *Am J Sports Med*. 2018;46(6):1343-1351. doi:10.1177/0363546518756976
4. National Institute for Health and Care Excellence. (2017). *Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee* (NICE guideline TA477) Available at https://www.nice.org.uk/guidance/ta477/resources/autologous-chondrocyte-implantation-for-treating-symptomatic-articular-cartilage-defects-of-the-knee-pdf-82604971061701 [Accessed 29 November 2021].
5. Mistry H, Connock M, Pink J, et al. Autologous chondrocyte implantation in the knee: systematic review and economic evaluation. Southampton (UK): NIHR Journals Library; 2017 Feb. (Health Technology Assessment, No. 21.6.) Available from: https://www.ncbi.nlm.nih.gov/books/NBK424075/ doi: 10.3310/hta21060
6. Carey JL, Remmers AE, Flanigan DC. Use of MACI (Autologous Cultured Chondrocytes on Porcine Collagen Membrane) in the United States: Preliminary Experience. *Orthop J Sports Med*. 2020;8(8):2325967120941816. Published 2020 Aug 12. doi:10.1177/2325967120941816
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8. von Keudell A, Han R, Bryant T, Minas T. Autologous Chondrocyte Implantation to Isolated Patella Cartilage Defects. *Cartilage*. 2017;8(2):146-154. doi:10.1177/1947603516654944
9. Krych AJ, Saris DBF, Stuart MJ, Hacken B. Cartilage Injury in the Knee: Assessment and Treatment Options. *J Am Acad Orthop Surg*. 2020;28(22):914-922. doi:10.5435/JAAOS-D-20-00266
10. Hinckel BB, Thomas D, Vellios EE, et al. Algorithm for Treatment of Focal Cartilage Defects of the Knee: Classic and New Procedures. *Cartilage*. 2021;13(1_suppl):473S-495S. doi:10.1177/1947603521993219

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