

## PHARMACY POLICY STATEMENT

### HAP CareSource™ Marketplace

<b>DRUG NAME</b>	<b>MACI (autologous cultured chondrocytes)</b>
BILLING CODE	J7330
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Inpatient/Outpatient hospital
STATUS	Prior authorization required

MACI® (autologous cultured chondrocytes on porcine collagen membrane) 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<sup>2</sup>). 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<sup>2</sup>; AND
6. Documentation of disabling knee pain that limits activities of daily living with symptom onset less than 3 years ago; AND
7. Member has tried and failed conservative therapy for at least 2 months, including physical therapy and anti-inflammatory medications; AND
8. The knee has stable alignment with the meniscus intact and normal joint space (per X-ray); AND
9. Documentation that the implantation will be followed by an appropriate, physician-prescribed rehabilitation program to which the member is expected to adhere; AND
10. 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
11. **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.

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].
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7. Niemeyer P, Albrecht D, Andereya S, et al. Autologous chondrocyte implantation (ACI) for cartilage defects of the knee: A guideline by the working group "Clinical Tissue Regeneration" of the German Society of Orthopaedics and Trauma (DGOU). *Knee*. 2016;23(3):426-435. doi:10.1016/j.knee.2016.02.001
8. Rosa D, Di Donato SL, Balato G, et al. How to Manage a Failed Cartilage Repair: A Systematic Literature Review. *Joints*. 2017;5(2):93-106. Published 2017 Jul 28. doi:10.1055/s-0037-1603900
9. 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

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