



autologous cultured
chondrocytes
on porcine
collagen membrane

PROCUREMENT AND REIMBURSEMENT GUIDE

Active cells help
restore active patients



FDA-APPROVED | autologous treatment for the repair of knee cartilage defects

MACI is an autologous biologic (using patient's own cells) not inventoried by the hospital and ordered directly from Vericel. Reimbursement information is provided in this packet. For additional information about MACI or to contact a Clinical Account Specialist, please call **800-453-6948**.

Nothing contained herein is intended, nor should it be construed, to suggest a guarantee of coverage or reimbursement for any product or service. Check with the individual insurance provider regarding coverage. Providers should exercise independent clinical judgment when selecting codes and submitting claims to reflect accurately the services rendered to individual patients.

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.

Important Safety Information: The most frequently occurring adverse reactions reported for MACI ($\geq 5\%$) 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.

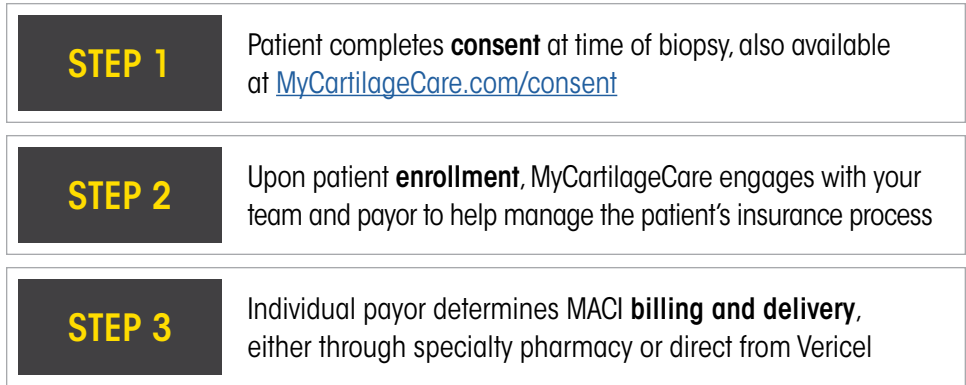


Please see [full Indication and additional Important Safety Information](#).
For more information, please see [Full Prescribing Information](#), or visit [MACI.com](#)



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PROCUREMENT PROCESS



Specialty Pharmacy

MACI implant is most often dispensed to facilities via specialty pharmacy. The specialty pharmacy incurs cost of MACI implant and seeks reimbursement from the payor.

Direct Purchase from Vericel

MACI may also be purchased directly from Vericel based on facility preference and/or patient's insurance carrier policy.

Specialty pharmacy bills payor for MACI implant

Facility bills payor for procedure

Facility bills payor for both MACI implant and procedure, Vericel requests a PO from the facility

HCPCS Level II Code: **J7330**
Autologous cultured chondrocytes, implant

CPT Code: **27412**
Autologous chondrocyte implantation, knee

CPT Code: **27412**
Autologous chondrocyte implantation, knee

HCPCS Level II Code: **J7330**
Autologous cultured chondrocytes, implant

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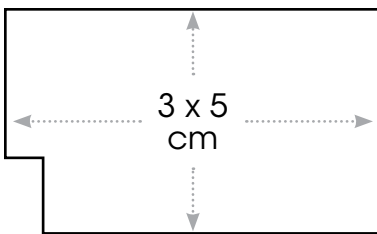
Please see [Indication and Important Safety Information](#). For more information, please see [Full Prescribing Information](#), or visit [MACI.com](#)



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IMPLANT SIZE AND ORDERING INFORMATION

Important note: MACI is an autologous (patient's own cells) product and is FDA-regulated as a physician administered biologic.

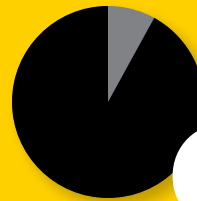


The **MACI implant** is available as a cellular sheet, 3 x 5 cm, with a 0.5-cm² section removed from the lower left-hand corner, consisting of autologous cultured chondrocytes on a resorbable Type I/III collagen membrane at a density of at least 500,000 cells per cm².

MACI—Number of Membranes Recommendation

1 Defect to be Treated		2 or 3 Defects to be Treated	
# of Membranes	Cumulative Lesion Area	# of Membranes	Cumulative Lesion Area
1	Equal to or less than 14 cm ²	1	Equal to or less than 10 cm ²
2	Greater than 14 cm ²	2	Greater than 10 cm ²

	1 Membrane	2 Membranes
HCPCS Level II Code	J7330	
NDC Code	69866-1030-5	69866-1030-8
NDC Billing Code (11-digit)	69866-1030-05	69866-1030-08
Vericel Part Number	81073	81074



92%

of MACI cases required a single MACI implant*

*MACI cases activated between January 2023 and December 2023. Data on file.

Call MyCartilageCare at **877-872-4643** to help navigate the payor procurement process.

Please see [Indication and Important Safety Information](#). For more information, please see [Full Prescribing Information](#), or visit [MACI.com](#)



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REIMBURSEMENT CODES

CPT Code:
27412

Autologous chondrocyte
implantation, knee

Device intensive procedure
(modifier may be required, payor specific)

HCPCS
Level II Code:
J7330

Autologous cultured
chondrocytes, implant

Biopsy HCPCS
Code: **S2112**

Arthroscopy, knee, surgical
for harvesting of cartilage
(chondrocyte cells)

MACI Implant Revenue Codes
(Payor Specific)
0278, 0279 or 0636

MACI Implant NDC Codes
69866-1030-5 (Single Membrane)
69866-1030-8 (Double Membrane)

NDC Billing Codes (11-digit)
69866-1030-05 (Single Membrane)
69866-1030-08 (Double Membrane)

Call MyCartilageCare at **877-872-4643** to help navigate
the payor procurement process.

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CMS-1500 form for physician offices and CMS-1450 (UB-04) claim form for the hospital outpatient department

Item 21 or Form Locator (FL) 67—Diagnosis Code

The appropriate ICD-10-CM code(s) should be entered for the MACI implant in Item 21 of the CMS-1500 form for physician offices or FL 67 of the CMS-1450 (UB-04) claim form for the hospital outpatient department.

Item 24D or FL 44—Medication Information

The appropriate HCPCS Level II Code J7330 Autologous cultured chondrocytes, implant should be entered for MACI in Item 24D of the CMS-1500 form for physician offices and FL 44 of the CMS-1450 (UB-04) claim form for the hospital outpatient department.

Item 19 or 24A shaded area and FL 43— Medication Information

Optional: In Item 19 or 24A shaded area of the CMS-1500 form for physician offices, or FL 43 of the CMS-1450 (UB-04) form for the hospital outpatient department, the full name of the medication administered, including strength if applicable (eg, MACI), dosage, basis of measurement (mg, units etc.) as well as the NDC (National Drug Code) on the package used (eg, 69866-1030-5) should be entered.

Please note: Payor NDC requirements and placement may vary. Check with payor.

Item 24D or FL 44—Administration Code

Since MACI is for autologous implantation only, an appropriate CPT administration code should be entered on a separate line in Item 24D of the CMS-1500 claim form for physician offices or FL 44 of the CMS-1450 (UB-04) claim form for the hospital outpatient department.

CPT Code: 27412 Autologous chondrocyte implantation, knee

Item 24F or FL 47—Medication Charge

HCPCS Level II Code: J7330 Autologous cultured chondrocytes, implant

Item 24G or FL 46—Medication Quantity

The quantity of medication administered should be indicated in Item 24G of the CMS-1500 form for physician offices or FL 46 of the CMS-1450 (UB-04) claim form for the hospital outpatient department. The number of units of the HCPCS code used should be entered, for example, 1 unit for 1 MACI.

Please Note: Billable units may vary by payor, please check with your payor for appropriate billable units to be used.

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Please see [Indication and Important Safety Information](#). For more information, please see [Full Prescribing Information](#), or visit [MACI.com](#)



MyCartilageCare.com/approval

1-877-872-4643

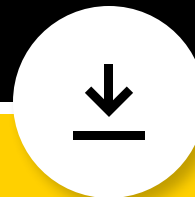
A patient support program for MACI providing insurance approval coordination and treatment information



MyCartilageCare offers support for your patients every step of the way including:

- Coordination of insurance coverage
- Education around MACI treatment
- Continued biopsy cell storage

MyCartilageCare.com/approval



STEP 1 Download and complete the patient enrollment form at MyCartilageCare.com/approval

STEP 2 Select the patient's insurance carrier and confirm the specific medical inclusion criteria

STEP 3 Fax the enrollment form and all supporting documentation to **855-803-9485**

MyCartilageCare will help determine patient prior authorization and MACI procurement requirements by working with the patient, your team, and the insurer. For assistance with patient insurance approvals, call your MyCartilageCare Case Manager at **877-872-4643**.

The health care provider is responsible for determining medical necessity, appropriate coding, and submission of accurate claims.

Please see [Indication and Important Safety Information](#).

For more information, please see [Full Prescribing Information](#), or visit MACI.com

Resources to assist with approvals and denial appeal can be found at MyCartilageCare.com/approval

- Insurer inclusion/exclusion criteria
- Dictation guide for common insurer inclusion criteria
- Letter of Medical Necessity assistance
- Peer-to-Peer guidance
- Patella clinical review
- Reimbursement guide



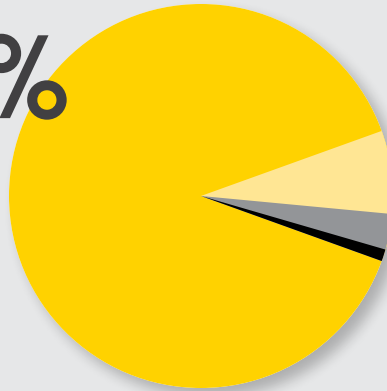
Call MyCartilageCare at **877-872-4643** to help navigate the payor procurement process

MACI insurance approval success rates*

MACI cases activated between January 2023 and December 2023

89%

of all MACI cases were approved on initial submission (average turnaround of 25-30 days)



7% Approved on appeal
(additional turnaround of 20-25 days)

3% Not appealed

1% Denied after appeal

MACI insurance approval specific to **patella cases**



- **88% Approved on initial submission** (25-30 days)
- **8% Approved on appeal** (+20-25 days)
- **4% Not appealed & 0% Denied after appeal**

*MACI cases activated between January 2023 and December 2023. Data on file. Insurance approval is defined as payor pre-authorization for the MACI procedure. Coverage, coding, and payment information is provided for informational purposes only and is subject to change. Nothing contained herein is intended, nor should it be construed, to suggest a guarantee of coverage or reimbursement for any product or service. Check with the individual insurance provider regarding coverage. Providers should exercise independent clinical judgment when selecting codes and submitting claims to reflect accurately the services rendered to individual patients.

MACI out-of-pocket expenses for commercially insured patients*

66%

of patients had \$0 in out-of-pocket expense

88%

of patients had <\$2,000 in out-of-pocket expense



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PROCUREMENT CHECKLIST

- After patient consent is obtained, the MyCartilageCare Case Manager will work with the patient to seek prior authorization from the payor.
- Prior authorization will be sought for the MACI implant (J7330) and the procedure (27412).
- Prior authorization for the procedure (27412) will be specifically for the implanting physician and facility.
- If the payor (and facility) allows for specialty pharmacy delivery, prior authorization for the MACI implant (J7330) will be sought through one of Vericel's in-network specialty pharmacy providers.
- If either the payor or facility requires the facility to be billed, prior authorization for the MACI implant (J7330) will be sought for your facility.
- If the MACI implant will be a facility bill process for the respective case, once prior authorization is obtained, MyCartilageCare will request a PO from your facility for the MACI implant.
- Prior to proceeding with a MACI implantation procedure, Vericel recommends a facility confirm reimbursement rates for MACI billing codes with their contracted payors.
- Your facility should also confirm which revenue code is required by their payor contracts for J7330 (i.e. 0278 or 0636).
- Update the facility's charge description master to reflect two MACI billing pathways for when MACI is:
 - a. purchased directly from Vericel by your facility (CPT 27412 and MACI J7330).
 - b. delivered to your facility via a specialty pharmacy provider (CPT 27412).
- Facilities should submit a claim only for 27412 when MACI is delivered by a specialty pharmacy provider.
- The specialty pharmacy provider will be submitting a claim to the payor for J7330.
- Facilities should submit a claim for 27412 and J7330 when the facility is purchasing the MACI implant.



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Active cells help restore active patients

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 cm²) 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.

For more information, please see [Full Prescribing Information](#), or visit [MACI.com](#)



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