Medical Policy:

Autologous Chondrocyte Implantation

POLICY NUMBER	LAST REVIEW
MG.MM.SU 37eC2	August 12, 2022

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

MACI® (autologous cultured chondrocytes on porcine collagen membrane) — an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. MACI is a cellular sheet that consists of autologous chondrocytes seeded on a 3 x 5 cm, resorbable porcine Type I/III collagen membrane. The active ingredients of MACI are the autologous cultured chondrocytes and porcine Type I/III collagen.

Guideline

Autologous chondrocyte implantation (ACI) is considered medically necessary for the repair of symptomatic, cartilaginous defects of the knee caused by acute or repetitive trauma when **all** of the following criteria are met:

1. Age 15–55 years of age
2. Presence of Grade III or Grade IV full thickness articular cartilage loss on a weight-bearing surface of the femoral condyle (medial, lateral or trochlear aspects)
3. Lesion is symptomatic (defined as lesion-related pain; swelling or catching/locking that limits activities of daily living)

4. The focal chondral defect size is between 1–10 cm
5. Inadequate response to prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty or osteochondral allograft/autograft)
6. The knee must be stable and aligned (a corrective procedure in combination with or prior to ACI may be necessary to ensure stability, alignment and normal weight distribution within the joint)
7. Prior to the procedure, there must be an expectation that the member will be able to fully participate in a prescribed post-op rehabilitation program necessary to insure optimal outcome

Note: Members can develop a new injury and another cartilage defect in the same knee. A subsequent or second procedure for a different defect of the same knee may be deemed medically necessary only if it is performed at least 6 months after the prior or initial procedure on that knee.

Documentation

All of the following must be documented and made available to the plan upon request:

1. Signs and symptoms limiting activities of daily living (pain, swelling, locking, crepitus, catching, giving-way, etc.)
2. Dates and outcomes of all previous surgical procedures on the knee (chondroplasty, drilling, microfracture, debridement, abrasion, etc.)
3. Pre-operative confirmation that the knee is stable and aligned with normal or optimal weight distribution within the joint
4. The location, dimensions, grade and depth of the identified focal chondral lesion, the condition of the surrounding articular cartilage

Documentation must support that prior to the procedure there was an expectation that the member would be able to fully participate in the post-op rehabilitation program necessary to insure optimal outcome.

Limitations and Exclusions

1. ACI is not considered medically necessary for the following indications due to insufficient evidence of therapeutic value:
    - Kissing lesions (includes degeneration or disease on the femoral and tibial aspect of the joint)
    - History of patellar/multiple defects
    - In joints other than the knee
2. Repeat ACI for the same lesion is not considered medically necessary, as it has not been sufficiently studied
3. ACI is not considered reasonable and medically necessary in the following circumstances:
    - As initial or first line surgical therapy
    - In a member who has had a previous total meniscectomy (Note: 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)
    - In a member with a known history of anaphylaxis to gentamicin or sensitivities to materials of bovine origin
    - In a member with infection at any of the proposed operative sites

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- In a member with a cartilaginous defect associated with osteoarthritis or inflammatory diseases or where an osteoarthritic or inflammatory process significantly and adversely affects the quality of the peri-lesional cartilage
- > 55 years of age (Clinical trials of MACI did not include subjects over the age of 55)

Procedure Codes

J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)
27412	Autologous chondrocyte implantation, knee

ICD-10 Diagnoses

M24.10	Other articular cartilage disorders, unspecified site
M25.861	Other specified joint disorders, right knee
M25.862	Other specified joint disorders, left knee
M25.869	Other specified joint disorders, unspecified knee
M94.8X8	Other specified disorders of cartilage, other site
M94.9	Disorder of cartilage, unspecified

References

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Revision History

Company(ies)	DATE	REVISION
ConnectiCare	Jan. 14, 2022	ConnectiCare retired MCG criteria for this service and adopted the clinical criteria of its parent corporation EmblemHealth
EmblemHealth	Aug. 14, 2020	Removed "Patellofemoral disorders" from the list of conditions for which ACI is not considered medically necessary, as it is already excluded under "History of patellar/multiple defects."
EmblemHealth	Oct. 13, 2017	Replaced Carticel (removed from the market) with MACI

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