Molina Clinical Policy
Autologous Chondrocyte Implantation for Knee Cartilage Lesions: Policy No. 347

Last Approval: 10/12/2023
Next Review Due By: October 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. 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 (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Cartilaginous Defects. The articular cartilage that covers the articulating bones in the knee, also called hyaline cartilage, is surrounded by an extracellular matrix that contains collagen and chondrocytes. Articular cartilage loss does not induce pain; however, it does result in pain in surrounding tissue, swelling, locking, and/or weakening. Articular cartilage defects can be categorized as chondral or osteochondral. Chondral defects are categorized further into partial thickness or full thickness, the latter of which extends to, but not into, the subchondral bone. Although partial-thickness defects do not typically cause noticeable symptoms, they can progress to full-thickness defects with time, increasing the risk of osteoarthritis (Hayes 2023; Mandl & Martin 2022).

There is currently no standard treatment for articular cartilage defects in the knee. Knee pain or symptoms from suspected chondral abnormalities are initially treated palliatively, without addressing the underlying diseases (Hayes 2023). Treatment options for symptomatic knee chondral abnormalities include the following three approaches:

- Palliative treatment techniques involve physical modifications, such as weight loss, muscle strengthening, physical rehabilitation, and the use of orthotics and/or knee braces. Physiotherapy frequently employs procedures such as laser therapy, ultrasound, pulsed electromagnetic fields, thermal stimulation, and electrical stimulation. Pharmacological treatment includes oral NSAIDs or topical ointments, chondroitin sulfate, or glucosamine. Surgical loose-body removal and arthroscopic debridement and lavage are also considered palliative treatment procedures because weightbearing is permitted immediately following surgery and the injured tissue is removed but not replaced or stimulated to self-repair.
- Microfracture (MFX) is the primary surgical bone marrow stimulation technique and the most commonly used surgical intervention for treating chondral defects of the knee. Other bone marrow stimulation techniques include drilling, abrasion, microfracture and autologous matrix induced chondrogenesis (AMIC).
- Surgical restorative procedures include matrix-induced autologous chondrocyte implantation (MACI) and other techniques not addressed in this policy, such as mosaicplasty, osteochondral autograft transfer system, bone marrow aspirate concentrate, and osteochondral allograft, autologous matrix induced chondrogenesis.

Autologous chondrocyte implantation (ACI), or matrix-induced autologous chondrocyte transplantation (ACT), is a surgical technique that aims to stimulate articular cartilage regeneration and fill cartilaginous defects with new hyaline tissue. 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 a multistage procedure that involves the use of autologous cultured chondrocytes on porcine collagen membrane. The procedure consists of two surgeries. A biopsy of healthy cartilage is obtained during the initial arthroscopic surgery. The cartilage sample is then sent to a laboratory, where chondrocytes from the biopsy are isolated and expanded in vitro for several weeks. After achieving an appropriate chondrocyte concentration, the chondrocytes are seeded onto a three-dimensional matrix. Then, in a subsequent surgical procedure, using an arthroscopic or mini-arthrotomy approach surgeons debride the damaged cartilage site and glue the seeded matrix to fill the entire defect (Hayes 2023).

Regulatory Status

ACI is a surgical procedure that is not regulated by the U.S. Food & Drug Administration (FDA). However, biological products are licensed by the FDA through the Biologics License Application (BLA) approval pathway (FDA 2021).

First-Generation ACI
Carticel™ (Vericel Corporation) received FDA approval in 1997 for their autologous cultured chondrocytes for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral, or trochlea) caused by acute or repetitive trauma in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty. **Carticel was phased out of the market in 2017 and was replaced by MACI, an ACI matrix-induced technique of the next generation.**

Second- and Third Generation ACI
Second- and third-generation technologies for implanting autologous chondrocytes in a biodegradable matrix are under development / testing, or accessible only outside the US. Some examples include: Atelocollagen (collagen gel; Koken)**;** BioCart II (ProChon Biotech)**;** Bioseed C (polymer scaffold; BioTissue Technologies)**;** CaReS (collagen gel; Ars Arthro)**;** Cartilix (polymer hydrogel; Biomet); Cartipatch® (agarose-alginate matrix, TBF Tissue Engineering)**;** ChondroCelect® (characterized chondrocyte implantation; TiGenix)**;** Chondron (fibrin gel; Sewon Cellontech); Hyalograft C (hyaluronic acid-based scaffold; Fidia Advanced Polymers)**;** NeoCart (ACI with a 3-dimensional chondromatrix; Histogenics); NOVOCART®3D (collagen-chondroitin sulfate scaffold; Aesculap Biologics).

Matrix-induced Autologous Chondrocyte Implantation (MACI) (Vericel 2022) received FDA approval via the BLA process in December 2016 and is indicated for: *the repair of symptomatic, single, or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults.*

In Europe and Asia, a number of second- and third-generation ACI products have been reported in clinical use, **however only MACI® has been FDA approved for use in the United States.**

COVERAGE POLICY

ACI (e.g., MACI® implant) for the treatment of articular cartilage defects of the knee **may be considered medically necessary** when **ALL** of the following clinical criteria are met:

1. Documented diagnosis of **ALL** the following:
   a. Treatment is for focal, full-thickness (Outerbridge Classification of Grade III or IV) unipolar lesions; **AND**
   b. Focal articular cartilage defect is caused by acute or repetitive trauma; **AND**
   c. Location of the defect is on the weightbearing surface of the femoral condyle (medial, lateral, trochlear); **AND**
   d. Size of the defect is at least 1.5 cm^2 in size

AND

2. Body Mass Index (BMI) of $\leq$ 35

AND

3. Adolescent age 15 or older with documented closure of growth plates, or adult up to age 55 who is not a candidate for total knee arthroplasty or other reconstructive knee surgery; **AND**

AND

Documentation of ALL of the following (#4-10 as follows):

4. Member is experiencing function-limiting pain including, but not limited to, loss of knee function which interferes with activities of daily living; **AND**

5. Physical examination findings include **ALL** of the following:

a. A stable knee with intact or reconstructed ligaments (ACL or PCL); **AND**
b. Normal tibial-femoral and/or patella-femoral alignment; **OR**
c. History of malalignment for deformity of the tibial femoral joint and/or patella maltracking that has been corrected and fixed.

AND

6. Failure of provider-directed, non-surgical medical management for at least three (3) months, as appropriate (e.g., weight reduction, physical therapy, braces and orthotics, intraarticular injection of hyaluronic acid derivatives, and nonsteroidal anti-inflammatory agents); **AND**

7. Inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft); **AND**

8. Minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge Grade II or less) and normal-appearing hyaline cartilage surrounding the border of the defect; **AND**

9. Absence of osteoarthritis, generalized tibial chondromalacia, and inflammatory arthritis or other systemic disease affecting the joints; **AND**

10. Member is capable of cooperating with post-operative weight bearing restrictions and completion of post-operative rehabilitation.

Limitations and Exclusions

ACI is **considered experimental, investigational, and unproven** for the following based on insufficient evidence.

1. For any indication not listed above.
2. Treatment of joints other than the knee (e.g., shoulder, hip, tibia, talus, glenohumeral).[Hu et al. 2021; Robinson et al. 2019]
3. As an initial or first-line treatment or surgical therapy.
4. History of total meniscectomy.
5. A cartilaginous defect (related to osteoarthritis, rheumatoid arthritis, or inflammatory diseases) or where an osteoarthritic or inflammatory process unfavorably affects peri lesional cartilage quality.
6. Osteochondritis dissecans.

Combination procedures, including but not limited to:

7. Meniscal allograft and ACI of the knee (evidence of efficacy has not been proven).
8. ACI and osteochondral autograft transfer system for repair of cartilage defects of the knee.
9. ACI and meniscus reconstruction for large chondral defect due to discoid lateral meniscus tear (long-term outcomes have not been established).
10. Combined ACI and osteochondral autograft transfer for large knee osteochondral lesion (long-term outcomes have not been established).
11. Autologous matrix-induced chondrogenesis (AMIC) for articular cartilage defects of the talus, patella-femoral lesions, and other osteochondral defects / lesions (lack of established evidence).
12. Two-stage bone and meniscus allograft and ACI for the treatment of unicompartmental osteoarthritis of the knee (evidence of efficacy has not been proven).

ACI is considered a **contraindication/exclusion** for the following:

1. Known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin.
2. Severe osteoarthritis of the knee, inflammatory arthritis, inflammatory joint disease.
3. Uncorrected congenital blood coagulation disorders.
4. 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.
5. Individual is unable to follow a physician-prescribed post-surgical rehabilitation program.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of

its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

A large body of evidence suggests that ACI may be an efficacious and a reasonably safe treatment for symptomatic articular cartilage defects of the knee. Treatment may improve symptoms in some patients over short- and intermediate-term follow-up. MACI appears to be generally safe with few safety concerns reported in the majority of the studies and complications occurring at rates comparable to other surgical interventions; however additional studies are needed to further evaluate the comparative safety of MACI. Furthermore, definitive patient selection criteria have not been fully defined, and its optimal place of therapy in the hierarchy of chondral defect treatments remains unclear.

MACI was approved by the FDA based on the findings of the **SUMMIT Study** and **the SUMMIT Study Extension.** The Summit Study was a prospective, Phase 3, multicenter, randomized, open-label comparison of MACI (n=72) and microfracture (n=72) over a two-year period. Saris et al. (2014) published the SUMMIT Study findings. From July 2008 to March 2012, the SUMMIT Study (NCT00719576) was conducted at 16 sites in 7 European countries. SUMMIT enrolled subjects ages 18 to 55 years (mean age 33.8 years and a mean BMI of 26 kg/m2) with at least one symptomatic Outerbridge grade III or IV focal cartilage defect on the medial femoral condyle, lateral femoral condyle, and/or the trochlea of at least 3 cm^2 in size and a baseline Knee Injury and Osteoarthritis Outcome Score (KOOS) pain score less than 55. Exclusion criteria included knee surgery within the previous six months (excluding diagnostic arthroscopy); modified Outerbridge Grade III or IV patellar or tibial defect(s); symptomatic musculoskeletal disorder in the lower limbs that could interfere with efficacy measurements in the target knee joint; total meniscectomy, meniscal allograft, or bucket handle tear or displaced tear requiring >50% meniscus removal in the target knee; malalignment necessitating osteotomy to correct tibiofemoral or patellofemoral alignment; Kellgren-Lawrence grade 3 or 4 osteoarthritis; inflammatory disease or other condition affecting the joints; or septic arthritis within one year prior to screening. At 104 weeks, the improvement with the MACI implant over microfracture in the co-primary endpoint subscores (pain and function) was clinically and statistically significant. The percentage of patients who responded to therapy at 104 weeks with at least a 10-point improvement in KOOS pain and function scores was substantially higher for the MACI group (87.5%) than the microfracture group (68.1%). Treatment failures (non-responders) were 12.5% for MACI and 31.9% for microfracture. MRI structural repair evaluations were done on 134 patients after 52 weeks and 139 patients after 104 weeks. MRI study of structural healing at both time points revealed that both treatment groups improved in defect filling, but there were no statistically significant differences. Two years following treatment, 83% of patients in the MACI group and 77% of patients in the microfracture group had greater than 50% of the defect depth filled. A second look arthroscopy and biopsy were performed on 116 patients (MACI implant n = 60; microfracture n = 56). The structural repair tissue was very good overall; nevertheless, the mean microscopic ICRS II overall assessment score of the 2 groups (63.8 versus 62.3) was not significantly different from one another.

The most frequently occurring adverse reactions (≥5%) reported for MACI 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 (Vericel 2022).

Brittberg et al. (2018) presented the results of the SUMMIT Extension Study (NCT01251588), which evaluated 5-year clinical effectiveness and safety of the 144 patients in the SUMMIT study: 65 MACI patients (90.3%) and 63 microfracture patients (87.5%). At the 5-year follow-up, 65 participants (65/65) in the MACI group and 59 subjects (59/63) in the microfracture group were still alive (total retention = 97%). The mean scores in KOOS pain and KOOS function were relatively steady in both therapy groups for an additional three years. The improvement of MACI over microfracture in the co-primary outcome of KOOS pain and function was clinically and statistically significant 5 years following therapy. Similar to the 2-year SUMMIT results, the MRI examination demonstrated an improvement in defect filling for both treatment groups; however, there were no statistically significant differences between treatment groups.

Systematic Reviews

There is insufficient evidence to support ACI for other joints (Robinson et al. 2019) or as a primary treatment for knee

cartilage lesions (Gou et al. 2020; Schuette et al. 2021).

Hu et al. (2021) conducted a meta-analysis to report various effects of ACI on osteochondral defects of the talus; this included 23 case series studies (458 patients) with osteochondral defects of the talus. Following ACI, the overall success rate for patients with talus osteochondral defects was 89%. The AOFAS score for patients with talus osteochondral defects after ACI was 86.33. The AOFAS score after ACI was significantly different when stratified by patient age. The study found that ACI has a relatively high success rate and improves the AOFAS score for those with talar osteochondral defects. It is recommended for clinical use.

Robinson et al. (2019) performed a systematic review of 9 studies using biologics for the treatment of femoroacetabular impingement (FAI). Inclusion criteria included studies assessing biologics used as adjuvant therapy to surgery for FAI treatment. Studies that included synthetic bone matrices or bone substitutes were excluded from the review. The 9 studies reviewed included 3 case studies, 1 retrospective cohort study, 3 prospective cohort studies, and 2 randomized controlled trials. Four studies included ACI as a biologic treatment for FAI. 674 participants were included in the review with a mean age of 37.6 years, male to female ratio of 1:1.2, and mean BMI of 25.5 kg/m2. Hip Outcome Score (HOS) modified Harris Hip Score (mHHS), Nonarthritic Hip Score (NAHS), and Western Ontario and McMaster Universities Arthritis Index (WOMAC) were used as outcome measurements. In one study significant improvement ($P < .001$) in mHHS was observed when ACI was used compared to debridement. Another study reported improved NAHS and WOMAC scores 6 weeks postoperatively and during the last follow-up (mean 16.1 months; 9.5-28.2 months range) when compared to preoperative scores). A study that compared ACI and AMIC found improvement in mHHS at 6 months postoperative compared to preoperative scores in both treatment groups. These improvements were maintained throughout the 5-year follow-up period. The systematic review concluded the use of ACI or AMIC showed favorable results for the treatment of FAI but noted limitations in these studies. Limitations of the review included low quality studies with only two RCTs included, small number of studies included, limited follow-up period (average 20.9 months), and inconsistencies between studies of biologics and surgical interventions used.

Smith et al. (2023) completed a systematic review of 19 studies with the goal to evaluate the outcomes of ACI in the knee joint. Inclusion criteria included studies observing biomechanical or functional outcomes for patients receiving ACI on the tibiofemoral and/or patellofemoral joints. There was a total of 767 patients included in the review with a mean age of 35.3±6.3 years, mean BMI of 26.4±2.5 kg/m2, and a mean defect size of 3.68±1.20 cm2. Outcomes measured included active or passive knee ROM, strength, and a non-strength related objective measurement of a functional activity. Results showed a statistically significant pre-operative and post-operative improvement in ROM that allowed patients to complete ADLs requiring deep flexion. The mean pre-operative ROM was 130.5±14.8° and the mean post-operative ROM was 136.1±10.2° at 57.2±36.9 months. Strength was reported in the form of straight leg raise assessments, knee extensor and flexor limb symmetry indices, and peak knee flexor and extensor strengths. The straight leg assessment was reported by one study and showed a statistically significant improvement ($p=0.0001$) 2-years post-operatively. Knee extensor and flexor limb symmetry indices were reported by 5 studies with a mean of 86.5±12.0% pre-operatively (reported by one study) and 92.0±12.7 post-operatively. One study reported both pre- and post-operative limb symmetry indices for peak knee extensor strength and found a statistically significant improvement ($p < 0.0001$). Peak knee flexor and extensor strength outcomes were reported in 6 studies with one study finding knee strength in the operative limb to be significantly lower than the contralateral limb at 4-years post-procedure. There was no statistical difference reported for knee torques. There was also a significant difference in the total isokinetic torque of the knee flexor and extensors between the operated leg and the contralateral leg at all post-operative follow-up periods. The functional activities commonly observed were the 6-minute walk test and the hop test. One study reported statistically significant improvements in the single and triple hop tests with no significant differences noted between traditional or accelerated rehabilitation. The 6-minute walk test was reported by 6 studies with only 3 studies reporting both pre- and post-operative distances. The mean pre-operative distance was 494.2±6.6m compared to a post-operative distance of 570.6±64.8m. Limitations noted by the researchers included small sample sizes, current literature being limited, and inconsistencies with control groups and rehabilitation protocols that made it difficult to assess the impact of ACI on functional activities.

Migliorini et al. (2020) performed a systematic analysis comparing the clinical outcomes of ACI and Mesenchymal Stem Cell (MSC) injections for treating focal chondral defects of the knee. The analysis comprised 43 articles (11 RCTs and 32 cohort studies) and data pooled from 3,340 procedures for analysis. First-generation (p-ACI) uses a periosteal patch harvested from the proximal tibia, second-generation (c-ACI) uses a graft containing type I/III collagen membrane, and third generation (m-ACI) uses autologous chondrocytes cultivated on type I and III collagen

membranes. Twelve studies reported p-ACI, eight c-ACI, and 13 m-ACI. The authors conclude that ACI procedures are a viable way to treat focal chondral defects of the knee, with considerable improvements from the first to third generation. This systematic review has limitations because the majority of included studies are retrospective or prospective, limiting the review to this level of evidence.

National and Specialty Organizations

The **American Academy of Orthopaedic Surgeons (AAOS)** published *The Management of Osteochondritis Dissecans of the Femoral Condyle* which indicates that ACI may be 'appropriate' for the treatment of osteochondritis dissecans (OCD) of the femoral condyles in patients presenting with pain, no mechanical symptoms (catching or locking), effusion, partially or totally closed growth plates, and imaging suggestive of stable and irreparable OCD fragments. It should be noted that while these guidelines stated that ACI "*may be appropriate*" for some patients with OCD but considers it "*rarely appropriate*" for most patients and these guidelines were not based on a systematic review of the evidence (AAOS 2015).

The **National Institute for Health and Care Excellence (NICE)** released the Technology appraisal guidance [TA477] for ACI for the treatment of symptomatic articular cartilage defects of the knee, including MACI and earlier-generation procedures. The panel suggested ACI as a therapy option for symptomatic patients who (NICE 2017):

- Have not undergone prior surgery to address the chondral defect,
- Have limited osteoarthritic involvement (as assessed by clinicians experienced in investigating knee cartilage damage using a validated measure for knee osteoarthritis), and
- Whose lesion exceeds 2 cubic centimeters (cm^2).

SUPPLEMENTAL INFORMATION

Scales Used to Determine Severity of Cartilage Defects of the Knee

International Cartilage Repair Society (ICRS 2000)

- Grade 0: Normal.
- Grade 1: Nearly Normal. Superficial lesions. Soft indentation and/or superficial fissures and cracks.
- Grade 2: Abnormal. Lesions extending down to <50% of cartilage depth.
- Grade 3: Severely Abnormal. Cartilage defects extending down >50% of cartilage depth as well as down to calcified layer and down to but not through the subchondral bone. Blisters are included in this Grade.
- Grade 4: Severely Abnormal. Defects of the full thickness of cartilage involving the subchondral bone.

Outerbridge Scale (Slattery & Kewon 2018)
The Outerbridge Scale was originally developed to classify the macroscopic changes of patellar chondromalacia. The scale was later modified to allow for the grading of all cartilage lesions. Studies that have evaluated the reliability of Outerbridge's classification system have used either arthroscopic video or another imaging comparison modality.

- Grade 1: Softening and swelling of the cartilage.
- Grade 2: Fragmentation and fissuring in an area half an inch or less in diameter.
- Grade 3: Fragmentation and fissuring in an area more than half an inch in diameter.
- Grade 4: Erosion of cartilage down to the bone.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

CPT	Description
27412	Autologous chondrocyte implantation, knee
29870	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)

HCPCS (Healthcare Common Procedure Coding System) Codes

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2023 Policy reviewed, no changes to criteria. Added code 29870. Updated Overview, Summary of Medical Evidence, and References.
10/12/2022 Policy revised. Literature reviewed and references updated. IRO Peer Review. 9/1/2022. Practicing Physician. Board-certified in Orthopedics. Notable revision include:
- Addition of criterion: Inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft).
- Addition of criterion: Member is capable of cooperating with post-operative weight bearing restrictions and completion of post-operative rehabilitation.
- Addition to 'Limitations and Exclusions' section in the 'Contraindications' list (per MACI labeling): Known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin; Severe osteoarthritis of the knee, inflammatory arthritis, inflammatory joint disease; Uncorrected congenital blood coagulation disorders; 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; Individual is unable to follow a physician-prescribed post-surgical rehabilitation program.
- Addition to 'Limitation and Exclusions' section in the 'experimental, investigational, and unproven' section: Osteochondritis dissecans (OCD)

10/13/2021 Policy reviewed, no changes to coverage criteria, updated Limitations & Exclusions, added 2021 literature review updates.
9/16/2020 Policy reviewed, no changes, updated references.
9/18/2019 New policy.

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