# MEDICAL POLICY

| | |
|---|---|
| **Medical Policy Title** | **Autologous Chondrocyte Implantation (ACI)** |
| **Policy Number** | **7.01.38** |
| **Current Effective Date** | October 15, 2025 |
| **Next Review Date** | June 2026 |

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

## POLICY STATEMENT(S)

I. Autologous chondrocyte implantation (ACI)/ autologous chondrocyte transplantation (ACT) using the matrix-induced/applied ACI (MACI) implant is **medically appropriate** when **ALL** the following criteria are met:

A. Body Mass Index (BMI) 35 or less;

B. Individual is age 15-55 years;

C. Absence of inflammatory arthritis or other systemic disease affecting the joints;

D. Presence of **ALL** of the following arthroscopic or imaging findings:

1. Kellgren-Lawrence Grade II or less on radiographs;
2. Normal articular cartilage at the lesion border (contained lesion); and
3. Full thickness distal femoral articular surface (i.e., medial condyle, lateral condyle, or trochlea) or patellar chondral defect of 1-10cm$^2$ in size that has been identified with **any** of the following:
   a. CT arthrogram;
   b. MRI and the Modified Outerbridge Classification is Grade III or IV;
   c. Arthroscopy and the Outerbridge Classification is Grade III or IV;

E. Absence of **BOTH** of the following findings:

1. Absence of an osteochondritis dissecans (OCD) lesion that requires bone grafting;
2. Absence of a Modified Outerbridge Classification Grade III or IV corresponding 'kissing lesion' defect on the distal femur (trochlea, condyles), patella, or tibia is required when performed for femoral and patellar chondral lesions;

F. Physical exam demonstrates **BOTH** of the following findings:

1. A stable knee with intact or reconstructed ligaments (anterior cruciate or posterior cruciate ligament) and menisci; (note: a concurrent ligament stabilization or meniscal procedure at the time of ACI would be acceptable);
2. Normal tibial-femoral or patella-femoral alignment;

G. Symptoms include function-limiting knee pain or loss of knee function which interferes with the ability to carry out age-appropriate activities of daily living;

H. Failure of provider-directed, non-surgical management for at least three (3) months ~~in~~ duration.

II. Autologous chondrocyte implantation is **not medically necessary** for **ANY** other indication or condition, including but not limited to the following:

A. Any knee joint surgery within six (6) months before screening, excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant;

B. Total meniscectomy, meniscal allograft, or bucket-handle tear or displaced tear requiring more than 50% removal of the meniscus in the target knee;

C. Septic arthritis within one (1) year before screening;

D. Known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin;

E. Uncorrected congenital blood coagulation disorders;

F. Cruciate ligament instability.

III. Hybrid autologous chondrocyte implantation (ACI) performed with osteochondral autograft transfer system (Hybrid ACI/OATS) technique is **investigational** for the treatment of osteochondral defects.

## RELATED POLICIES

Corporate Medical Policy

7.01.59 Osteochondral Grafting of the Knee

11.01.03 Experimental or Investigational Services

## POLICY GUIDELINE(S)

Not Applicable

## DESCRIPTION

Destruction of the articulating surface of the synovial joint of the knee results in increased pain and loss of function to the joint. Damaged articular cartilage fails to heal on its own, making repair of articular surfaces difficult. Autologous chondrocyte implantation (ACI) is a surgical treatment for patients with deep cartilage defects in the knee. The procedure requires two separate surgeries, the collection and culture of an individual's own articular cartilage cells (i.e., chondrocytes) followed by the implant into the cartilage defect with the intent that the cultured cells will contribute to the regeneration and repair of the articular surface.

The first- generation approach to ACI was known as Carticel. The Carticel approach creates a suspension of cells that is then injected into the defect, followed by the application of a periosteal

flap or collagen membrane. This procedure requires suturing to create a seal and due to this, cell leakage is a potential issue. Carticel received U.S. Food & Drug Administration (FDA) approval for the culturing of chondrocytes through a biologics license. The approval restricted its use for the repair of symptomatic cartilaginous defects of the femoral condyle (medial, lateral, or trochlear), caused by acute or repetitive trauma in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure.

Methods to improve the Carticel/ACI procedure have since been developed and now have replaced the first-generation approach including the use of a scaffold or matrix-induced/applied ACI (MACI) composed of biocompatible carbohydrates, protein polymers or synthetics (e.g., matrix based ACI, Hyalograft C, Cartipatch). With MACI, the chondrocytes are seeded onto a bio-resorbable collagen sponge. The only FDA-approved MACI product to date is supplied in a sheet, which is cut to size and fixed with fibrin glue. This method allows for a smaller incision, prevents the need for suturing and testing for water tightness, and is therefore considered to be technically easier and less time-consuming than its predecessor. The entire MACI procedure consists of four steps:

(1) initial arthroscopy and biopsy of normal cartilage;

(2) culturing of chondrocytes on an absorbable collagen matrix;

(3) a separate arthrotomy to place the implant and create a periosteal flap; and

(4) postsurgical rehabilitation.

The initial arthroscopy may have been scheduled as a diagnostic procedure. In some cases, if a cartilage defect is identified, it may prompt a biopsy of normal cartilage in anticipation of a possible chondrocyte transplant. The biopsied material is then sent for culturing and returned to the hospital the day before the implantation procedure (i.e., arthrotomy) is scheduled to take place.

Minced Cartilage Repair Technique

Two similar alternative second generation techniques have been developed-the cartilage autograft implantation system (DePuy Mitek), and DeNOVO NT Graft (Zimmer Inc.). These two techniques utilize minced pieces of cartilage which are seeded over a scaffold to create structural and mechanical protection. The DeNOVO NT Graft utilizes minced juvenile fresh allograft tissue obtained from donated cadavers. There are no published well-designed studies upon which to establish the minced cartilage repair technique as a safe and effective procedure over the standard techniques.

Hybrid MACI/OATS

Osteochondral autograft transfer systems (OATS) are an alternative method of treatment for the repair of osteochondral defects and are themselves addressed in an alternative medical policy, refer to CMP#7.01.59 Osteochondral Grafting of the Knee. A hybrid procedure consisting of MACI and OATS has been investigated. Typically used for the repair of larger sized lesions, OATS is a technique where one or more small cores of osteochondral tissue are taken from non-weight-bearing areas of bone, typically from the knee and are pressed into a lesion that has been surgically prepared. The hybrid procedure utilizing both MACI and OATS entails restoring cartilage height with the use of the cores, the addition of a covering and improvement in chondral integration with the integration of the chondrocytes.

Classification Systems

The Outerbridge Classification is a system that has been developed for judging articular cartilage injury to the knee. This system allows delineation of varying areas of chondral pathology, based on the qualitative appearance of the cartilage surface as viewed by direct visualization intraoperatively, and can assist in identifying those injuries that are suitable for repair techniques. The characterization of cartilage in this system is as follows:

1. Grade I – softening with swelling;
2. Grade II – fragmentation and fissuring less than one square centimeter (1 $cm^2$);
3. Grade III – fragmentation and fissuring greater than one square centimeter (1 $cm^2$);
4. Grade IV – subchondral bone exposed.

The Modified Outerbridge Classification is a system that has been developed for judging articular cartilage injury to the knee. This system allows delineation of varying areas of chondral pathology, based on the qualitative appearance of the cartilage surface, and can assist in identifying those injuries that are suitable for repair techniques. The characterization of cartilage in this system is as follows:

1. Grade I – softening with swelling;
2. Grade II – fragmentation and fissuring that do not exceed one square centimeter (1 $cm^2$);
3. Grade III – fragmentation and fissuring greater than one square centimeter (1 $cm^2$);
4. Grade IV – subchondral bone exposed.

The Kellgren-Lawrence Grading System is a radiographic grading system that has been developed for describing osteoarthritic changes to the knee. When used, the radiographic findings are typically reported within one of the following categories:

1. Grade 0 – No radiographic features of osteoarthritis are present;
2. Grade I – Doubtful narrowing of joint space and possible osteophytic lipping;
3. Grade II – Definite osteophytes and possible narrowing of joint space;
4. Grade III – Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis, and possible deformity of bone contour;
5. Grade IV – Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour.

## SUPPORTIVE LITERATURE

Autologous Chondrocyte Implantation

There is sufficient data published in the peer-reviewed literature to conclude that autologous chondrocyte transplantation results in relief of symptoms and improved function in patients who had failed conservative management and arthroscopic or other surgical treatments. Several studies include reports of histological examinations of the graft site showing stable hyaline cartilage after

surgery. Studies in the United States enrolled patients between the ages of 15 and 45 years.

K. Zaslav and colleagues (2009) aimed to assess the effectiveness of ACI in patients who failed prior treatments for articular cartilage defects of the knee. STAR was a prospective, open-label, four-year study of 154 patients (mean age: 35 years; 69% male) from 29 clinical centers. Each patient served as the patient's own control, undergoing ACI after having failed or experienced an inadequate response to a prior cartilage repair procedure. Outcomes included change from baseline in knee function, knee pain, quality of life, and overall health. Duration of benefit after ACI was compared with the failed prior non-autologous chondrocyte implantation procedure. A total of 126 patients (82%) completed the protocol. Seventy-six percent of patients were treatment successes at study-end, while 24% were deemed treatment failures. Preoperative mean knee pain score was 3.0 (SD, 1.8; 0 = severe, 10 = normal). Mean improvements were observed from baseline to all time points ($P < .001$) for all outcome measures. Preoperative to 48-month values, respectively, were as follows: On the Knee injury and Osteoarthritis Outcome Score (KOOS) subscales of pain: 48.7 to 72.2; other symptoms: 51.8 to 70.8; sports/recreation: 25.8 to 55.8; knee quality of life: 20.9 to 52.2; and activities of daily living: 58.6 to 81.0. On the Modified Cincinnati Overall Knee Score: 3.3 to 6.3; on the Visual Analog Scale: 28.8 to 69.9; and on the SF-36 Overall Physical Health Score: 33.0 to 44.4. Seventy-six patients (49%) had subsequent surgical procedure(s), predominantly arthroscopic. The authors concluded that patients with moderate-to-large chondral lesions with failed prior cartilage treatments can expect sustained and clinically meaningful improvement in pain and function after ACI.

Migliorini and colleagues conducted a systematic review of the literature in 2022 to evaluate the safety and efficacy of ACI for chondral defects of the knee in skeletally immature patients. A total of 9 studies (three prospective and six retrospective studies) representing 251 procedures were analyzed for patient reported outcome measures and complications. The mean age of the patients was 16.4 ±0.7 years, and the mean length of follow up was 44.2±29.4 months. Studies with follow up less than 12 months were not included in the review. Authors analyzed the KOOS score, Visual Analog Scale (VAS), Tegner Activity Scale, Lysholm Knee Score, and the International Knee Document Committee (IKDC) Score. Increases were identified in the KOOS (+41.9/100 [P=0.003)]), IKCD (+33.2/100 [P=<0.0001]), and Lysholm (+20.6/100 [P=0.02]). The VAS score was reduced by 3.6/10 (P=0.004) points. There was no statistically significant improvement noted in the Tegner scale. Authors expressed concern with the rate of complications. More than 12% of patients demonstrated graft hypertrophy and 5.6% of procedures were considered failures. It is believed that these numbers were underestimated given an unclear reporting of complications in several of the studies. Several other limitations of the studies were noted, including the lack of control groups creating a moderate risk of bias. There was also a limited sample size, and lack of quantitative data to conduct analyses. Further, there was a difference in the method of membrane application (suture versus fibrin glue) between studies which may have negatively impacted the results. Authors concluded that ACI of chondral defects in the knees of skeletally immature patients is effective in improving patient reported outcome measures, however the review was granted a level of evidence of III, noting that the safety profile of ACI in skeletally immature patients is controversial and requires further investigation.

<u>MACI</u>

The approval of MACI is based on the SUMMIT study (Superiority of MACI implant versus Microfracture Treatment in patients with symptomatic articular cartilage defects in the knee). In the open-label, multi-center Phase 3 SUMMIT study, 144 patients with symptomatic articular cartilage defects in the knee were randomized to receive treatment with MACI implant or microfracture bone marrow stimulation (MFX) and followed for two years (Saris et al 2014). The study found that treatment with MACI was clinically and statistically significantly better, as measured by greater improvement in KOOS pain and function (SRA) scores in the MACI group compared to the MFX groups (p=0.001) with similar structural repair tissue and safety. The SUMMIT study investigators concluded that "MACI offers a more efficacious alternative to MFX, with a similar safety profile for the treatment of symptomatic articular cartilage defects of the knee." Patients from the two-year SUMMIT study had the option to enroll in a three-year follow-up study (extension study). A majority of the patients who completed the SUMMIT study also participated in the extension study. Overall efficacy data support a long-term clinical benefit from the use of MACI in patients with cartilage defects of the knee.

Three-year follow-up results of the SUMMIT extension study were presented at the 2015 American Academy of Orthopaedic Surgeons (AAOS) annual meeting. In the SUMMIT extension trial, 128 patients (men and women aged 18 to 55 years) from the original SUMMIT study continued to be followed. The co-primary endpoints of the extension study are change in KOOS pain and function scores at year three, the same primary endpoint from the two-year SUMMIT trial. Patients treated with MACI versus MFX continue to show a statistically significant improvement from baseline in the co-primary endpoint of KOOS pain and function at year three ($p = 0.046$), with higher responder rates in the MACI group (81.5%) than in the MFX group (66.7%). Patients treated with MACI versus MFX also showed significant improvement in knee-related quality of life and other measures. The authors concluded that "the co-primary endpoints of pain and function showed significant improvement with MACI, which was statistically significantly better than with MFX." The incidence of treatment-emergent adverse events and serious adverse events was similar between treatment groups at year three, and no unexpected safety findings were reported.

Based on mid-term outcomes that approximate those of first-generation ACI and the lack of alternatives, second-generation ACI may be considered an option for large, disabling, full-thickness cartilage lesions of the knee. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

ACI for Joints Other than the Knee

The evidence reported on ACI for individuals who have focal articular cartilage lesions in joints other than the knee is limited. Relevant outcomes are symptoms, functional outcomes, implant survival, quality of life, and resource utilization. ~~The greatest amount of literature is for ACI of the talus~~. The evidence is insufficient to determine the effects of the technology (ACI for joints other than knee) on health outcomes.

A study conducted by Viglione and colleagues published in 2024 assessed the long-term efficacy of ACI for osteochondral lesions of the talus to demonstrate durability by comparing the American Orthopedic Foot and Ankle Society (AOFAS) ankle-hindfoot score, numeric rating scale (NRS), and Tegner scores for 11 patients who were evaluated at 1, 3, 10, and at a minimum a final follow-up of

20 years. There was a significant improvement in AOFAS score from baseline through the last follow-up, with 40.4 ± 19.8 to 89.3 ± 15.2 at 1 year ($p < 0.0005$), 94.4 ± 6.8 at 3 years ($p < 0.0005$), 94.7 ± 6.4 at 10 years ($p < 0.0005$), and 82.7 ± 12.9 at the final follow up ($p < 0.0005$). The NRS also showed significant improvements compared to baseline-from 7.8 ± 0.7 to 4.8 ± 2.1 ($p < 0.0005$). None of the patients underwent arthrodesis or joint replacement surgeries following ACI. Authors concluded that ACI is a effective treatment option for patients with osteochondral lesions of the talus, with long term clinical improvements noted. The small patient sample did not allow for an analysis of other factors that may have impacted the study outcomes, including sex, age and previous surgical interventions. Further studies are warranted.

In a 2025 systematic review, Mahatme and colleagues aimed to investigate the outcomes of patients who had been treated with MACI during arthroscopy of the hip for the treatment of acetabular chondral lesions caused by femoroacetabular impingement syndrome. The review included a query of studies including patient reported outcomes of MACI during hip arthroscopy, as well as lesion classification, surgical treatment, revision arthroscopy and conversion to total hip arthroplasty. A qualitative sub-analysis compared patients who were treated with MACI with those treated with microfracture. A total of four studies met the required inclusion criteria which was representative of 209 hips, that had undergone MACI. The mean post-operative follow up time frame was between 1 and 8 years, with a mean patient age from 34.3 to 45 years. Three of four studies reported the modified Harris Hip Score, all of which reported statistically significant improvements at follow-up. Of the four studies, two compared MACI with microfracture alone. Authors noted that there were no conversions to total hip arthroplasty in the MACI groups, while rates of conversion were variable among microfracture groups, reporting anywhere from two to 32.6%, Authors concluded that the use of MACI for the treatment of femoroacetabular impingement syndrome and acetabular chondral lesions improves patient reported outcomes and lowers rates of secondary surgeries required. The study was granted a IV for level of evidence given included studies also were considered low levels of evidence (III and IV). Significant heterogeneity between studies in terms of follow up periods and surgical techniques, as well as an overall small sample size contributed to the limitations.

Hybrid Technique

A review conducted by Duif and colleagues in 2015 included a search of PubMed based literature using the terms mosaicplasty, osteochondral transplantation or OATS AND autologous chondrocyte transplantation or ACI OR matrix-associated autologous chondrocyte implantation or MACI and combination. Only two relevant publications were identified. Although both publications reported satisfying results on the postoperative functional outcome, the authors determined that the simultaneous use of different techniques for cartilage repair may provide alternate solutions, but statistically valid data and prospective studies are required to make a general recommendation.

In 2019, Jones and colleagues, in a technical note, describe a ACI "sandwich technique" in which MACI is paired with autologous bone grafting for osteochondral lesions of the femoral trochlea. The authors noted successful early results for small segmental defects, but also that few studies have evaluated outcomes, and that further reporting is forthcoming.

## PROFESSIONAL GUIDELINE(S)

In 2017, The National Institute for Health and Care Excellence (NICE) published guidance on autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee, recommending it be used as an option only if:

I. The person has not had previous surgery to repair articular cartilage defects;

II. There is minimal osteoarthritic damage to the knee (as assessed by clinicians experienced in investigating knee cartilage damage using a validated measure for knee osteoarthritis;

III. The defect is over $2cm^2$;

IV. The procedure is done at a tertiary referral centre.

In 2023, the American Academy of Orthopaedic Surgeons (AAOS) published guidelines on the diagnosis and treatment of osteochondritis dissecans. The guidelines do not specifically address a recommended cartilage repair technique in patients who have unsalvageable osteochondritis dissecans lesion or those with an unsalvageable fragment.

## REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates vaccines, blood and blood products, and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety, efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: https://www.fda.gov/vaccines-blood-biologics [accessed 2025 May 19]

Carticel received FDA approval in 1997 through a biologics license application for the culturing of chondrocytes. The approval restricted Carticel to use for the repair of symptomatic cartilaginous defects of the femoral condyle (medial, lateral, or trochlear), caused by acute or repetitive trauma in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure. The product was phased out with the development of MACI.

In December 2016, the FDA approved MACI (autologous cultured chondrocytes on porcine collagen membrane) for the repair of symptomatic single or multiple full-thickness cartilage defects of the knee, with or without bone involvement, in adults. MACI is the first FDA-approved, cellularized, scaffold product that applies tissue engineering processes to grow cells on scaffolds using healthy cartilage tissue from the patient's own knee. The package insert includes the following contraindications: 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, or uncorrected congenital blood coagulation disorders, prior knee surgery (within 6 months), excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant, inability to cooperate with a physician-prescribed post-surgical rehabilitation program.

## CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than

policy updates).

- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

**CPT Codes**

| Code | Description |
|---|---|
| 27412 | Autologous chondrocyte implantation, knee |



**HCPCS Codes**

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

**ICD10 Codes**

| Code | Description |
|---|---|
| M12.561-M12.569 | Traumatic arthropathy, knee (code range) |
| M17.0-M17.9 | Osteoarthritis of knee (code range) |
| M23.50-M23.52 | Chronic instability of knee (code range) |
| M23.8X1 – M23.8X9 | Other internal derangements of knee (code range) |
| M23.90-M23.92 | Unspecified, internal derangement of knee (code range) |
| M25.261-M25.269 | Flail joint, knee (code range) |
| M25.361-M25.369 | Other instability, knee (code range) |
| M25.861-M25.869 | Other specified joint disorder, knee (code range) |
| M85.9 | Disorder of bone density and structure, unspecified |
| M89.8X6 | Other specified disorders of bone, lower leg |

| Code | Description |
|---|---|
| M89.9 | Disorder of bone, unspecified |
| M93.20 | Osteochondritis dissecans of unspecified site |
| M93.261-M93.269 | Osteochondritis dissecans knee (code range) |
| M94.8X6 | Other specified disorders of cartilage, lower leg |
| M94.9 | Disorder of cartilage, unspecified |

## REFERENCES

Almqvist KF, et al. Treatment of cartilage defects in the knee using alginate beads containing human mature allogeneic chondrocytes. Am J Sports Med. 2009 Oct;37(10):1920-9.

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. The diagnosis and treatment of osteochondritis dissecans-evidence based clinical practice guideline. 2023 Dec 01 [accessed 2025 May 19]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/osteochondritis-dissecans/osteochondritis-dissecans-rapid-update-2023.pdf

Bentley G, et al. Minimum ten-year results of a prospective randomized study of autologous chondrocyte implantation versus mosaicplasty for symptomatic articular cartilage lesions of the knee. J Bone Joint Surg Br. 2012 Apr;94(9):504-9.

*Bhosale AM, et al. Midterm to long-term longitudinal outcome of autologous chondrocyte implantation in the knee joint: a multilevel analysis. Am J Sports Med. 2009 Nov;37 Suppl 1:131S-8S.

Carey JL, et al. Autologous chondrocyte implantation as treatment for unsalvageable osteochondritis dissecans: 10- to 25-year follow-up. Am J Sports Med. 2020 Apr;48(5):1134-1140.

Clar, et al. Clinical and cost-effectiveness of autologous chondrocyte implantation for cartilage defects in knee joints: systematic review and economic evaluation. Health Tech Assess. 2005;9(47).

Duif, C et al. Combination of autologous chondrocyte implantation (ACI) and osteochondral autograft transfer system (OATS) for surgical repair of larger cartilage defects of the knee joint. A review illustrated by a case report. Technol Health Care. 2015;23(5):531-537.

Ebert JR, et al. Minimum 10-year clinical and radiological outcomes of a randomized controlled trial evaluating 2 different approaches to full weightbearing after matrix-induced autologous chondrocyte implantation. The American Journal of Sports Medicine. 2020; 48(1):133-42.

Epanomeritakis IE, et al. The use of autologous chondrocyte and mesenchymal stem cell implants for the treatment of focal chondral defects in human knee joints-a systematic review and meta-analysis. International Journal of Molecular Sciences. 2022 Apr 6;23(7):4065. doi: 10.3390/ijms23074065.

Giannini S, et al. Surgical treatment of osteochondral lesions of the talus by open-field autologous chondrocyte implantation: a 10-year follow-up clinical and magnetic resonance imaging T2-mapping evaluation. Am J Sports Med. 2009 Nov;37 Suppl 1:112S-8S.

Gooding CR, et al. A prospective, randomized study comparing two techniques of autologous chondrocyte implantation for osteochondral defects in the knee: Periosteum covered versus type I/III collagen covered. Knee. 2006;13:203-10.

Gou GH, et al., Autologous chondrocyte implantation versus microfracture in the knee: a meta-analysis and systematic review. Arthroscopy: The Journal of Arthroscopic and Related Surgery. 2020 Jan; 36(1): 289-203.

Gowd AK, et al. Cartilage restoration of bipolar lesions within the patellofemoral joint delays need for arthroplasty: a systematic review of rates of failure. Arthroscopy, Sport Medicine Rehabilitation. 2021 Jun 14;3(4): 1189-1197.

Jones KJ, et al. Comparative effectiveness of cartilage repair with respect to the minimal clinically important difference. Am J Sports Med. 2019 Nov;47(13):3284-3293.

Kim MK, et al. Autologous chondrocyte implantation in the knee using fibrin. Knee Surg Sports Traumatol Arthrosc. 2009 Sep 18 [Epub ahead of print].

Loken S, et al. Autologous chondrocyte implantation to repair knee cartilage injury: ultrastructural evaluation at 2 years and long-term follow-up including muscle strength measurements. Knee Surg Sports Traumatol Arthrosc. 2009 Nov;17(11):1278-88.

Mahatme RJ, et al. Autologous matrix-induced chondrogenesis for the treatment of hip acetabular chondral lesions demonstrates improved patient reported outcomes and low rates of secondary surgeries at short-term follow-up: a systematic review. Arthroscopy. 2025 April;41(4):1143-1152,

Migliorini F, et al. Autologous chondrocyte implantation in the knee is effective in skeletally immature patients: a systematic review. Knee Surg Sports Traumatol Arthrosc. 2023;31:2518-2525.

Migliorni N, et al. Surgical management of focal chondral defects of the knee: a Bayesian network meta-analysis. Journal of Orthopaedic Surgery and Research. 2021(16):543-556.

Nam EK, et al. Autologous chondrocyte implantation of the ankle: 2-to-5-year follow-up. Am J Sports Med. 2009 Feb;37(2):274-84.

National Institute for Health and Clinical Excellence (NICE) [Internet]. Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee. TA477. 2018 March 7 [https://www.nice.org.uk/guidance/ta508] accessed 05/14/24.

Saris DB, et al. Treatment of symptomatic cartilage defects of the knee: characterized chondrocyte implantation results in better clinical outcome at 36 months in a randomized trial compared to microfracture. Am J Sports Med. 2009 Nov;37 Suppl 1:10S-9S.

Snow M, et al. A randomized trial of autologous chondrocyte Implantation versus alternative forms of surgical cartilage management in patients with a failed primary treatment for chondral or osteochondral defects in the knee. The American Journal of Sports Medicine. 2023 Feb;51(2):367-378.

Van Assche D, et al. Physical activity levels after characterized chondrocyte implantation versus microfracture in the knee and the relationship to objective functional outcome with 2-year follow-up.

Am J Sports Med. 2009 Nov;37 Suppl 1:42S-9S.

Viglione V, et al. Autologous chondrocyte implantation for the treatment of osteochondral lesions of the talus: what happens after 20 years? Foot and Ankle Surgery. 2024 April 13;30:546-551.

Witstein JR, et al. OrthoInfo [Internet]. Articular Cartilage Restoration- from the American Academy of Orthopaedic Surgeons. 2023 Feb [accessed 2025 May 05]. Available from: https://orthoinfo.aaos.org/en/treatment/articular-cartilage-restoration/

Zamborsky and Danisovic. Surgical techniques for knee cartilage repair: an updated large-scale systematic review and network meta-analysis of randomized controlled trials. Arthroscopy. 2020 Mar;36(3):845-858.

Zaslav K, et al. A prospective study of autologous chondrocyte implantation in patients with failed prior treatment for articular cartilage defect of the knee: results of the Study of the Treatment of Articular Repair (STAR) clinical trial. Am J Sports Med. 2009 Jan;37(1):42-55.

## SEARCH TERMS

Carticel, Matrix-induced, MACI, Minced cartilage, Neocartilage, Scaffold-induced

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based upon our review, autologous chondrocyte implantation is not addressed in National or Regional Medicare coverage determinations or policies.

## PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

## POLICY HISTORY/REVISION

### Committee Approval Dates

10/18/01, 01/17/02, 03/20/03, 01/15/04, 01/20/05, 11/17/05, 07/20/06, 06/21/07, 05/14/08, 04/16/09, 05/27/10, 05/19/11, 05/24/12, 04/18/13, 03/20/14, 03/19/15, 02/18/16, 04/20/17,

| 04/18/18, 06/21/18, 06/20/19, 08/20/20, 06/17/21, 05/19/22, 05/18/23, 10/17/24, 06/26/25 | |
|---|---|
| **Date** | **Summary of Changes** |
| 06/26/25 | • Annual review. Policy intent unchanged. |
| 01/01/25 | • Summary of changes tracking implemented. |
| 10/18/01 | • Original effective date |