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Original Effective Date: 09/01/01

Reviewed: 08/28/25

Revised: 09/15/25

Subject: Autologous Chondrocyte Implantation (ACI)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Damaged articular cartilage typically fails to heal on its own and can be associated with pain, loss of function, and disability and may lead to debilitating osteoarthritis over time. These manifestations can severely impair activities of daily living and adversely affect quality of life.

With autologous chondrocyte implantation (ACI), a region of healthy articular cartilage is identified and biopsied through arthroscopy. The tissue is sent to a facility licensed by the U.S. Food and Drug Administration (FDA) where it is minced and enzymatically digested, and the chondrocytes are separated by filtration. The isolated chondrocytes are cultured for 11 to 21 days to expand the cell population, tested, and then shipped back for implantation. Under general anesthesia, an arthrotomy is performed, and the chondral lesion is excised up to the normal surrounding cartilage. Methods to improve the first-generation ACI procedure have been developed, including the use of a scaffold or matrix-induced autologous chondrocyte implantation (MACI), composed of biocompatible carbohydrates, protein polymers, or synthetics. The only FDA-approved MACI product to date is supplied in a sheet, which is cut to size and fixed with fibrin glue. This procedure is considered technically easier and less time-consuming than the first-generation technique, which required suturing of a periosteal or collagen patch and injection of chondrocytes under the patch.

Summary and Analysis of Evidence: Bartlett et al (2005) reported on a randomized comparison between MACI and autologous chondrocyte implantation with a collagen cover in 91 patients. Overall, results were comparable for both treatments. The modified Cincinnati Knee Rating System score improved by 17.6 points in the autologous chondrocyte implantation group and by 19.6 points in the MACI group. Visual analog scale scores improved from 6.0 to 4.3 in the autologous chondrocyte implantation group and from 6.0 to 4.1 in the MACI group. Factors associated with worse clinical outcomes were a failed prior procedure, duration of symptoms, and patient age. Second-look arthroscopy at 1 year for 42 patients showed excellent-to-good International Cartilage Repair Society

scores in 79.2% of autologous chondrocyte implantation and in 66.6% of MACI patients. The authors did not report whether the study was adequately powered for this comparison. Histology from 14 autologous chondrocyte implantation and 11 MACI patients showed similar percentages of hyaline-like cartilage (42.9% autologous chondrocyte implantation, 36.4% MACI).

The SUMMIT trial was the pivotal, industry-sponsored, multicenter randomized open-label trial; it was reported by Saris et al (2014) and compared MACI with microfracture (MF) for larger cartilage defects (≥3 cm2), which typically fare worse than smaller lesions when treated with MF. 144 patients included had at least 1 symptomatic grade III or IV focal cartilage defect on the femoral condyles or trochlea, a stable knee, an intact or partial meniscus, and a moderate-to-severe KOOS pain value (<55). The average lesion size was 4.8 cm2 (range, 3 to 20 cm2), and 34.6% of patients had undergone a prior marrow stimulation procedure. At 2-year follow-up, the MACI group had significantly better subscores for KOOS pain and function in sport and recreation, as well as the other KOOS subscales (function in daily living, knee-related quality of life, other symptoms). With response to treatment defined as a 10-point improvement in both the KOOS pain and function subscales, significantly more patients in the MACI group responded to treatment (87.5%) than in the MF group (68.1%). There were no significant differences between groups for cartilage repair, as measured by second-look arthroscopy, biopsy, or magnetic resonance imaging (MRI).

A 2022 systematic review (Angele et al, 2022) reported outcomes of randomized trials of cartilage repair techniques for localized cartilage defects of the knee with a minimum 5-year follow-up. The 6 included RCTs comprised 520 patients, with mean follow-up ranging from 5 to 16 years. One trial (SUMMIT) compared MACI to MF, and 3 compared other autologous chondrocyte implantation techniques to either MF or osteochondral autograft transplantation. The trial comparing MACI to MF indicated superior outcomes in the Knee Injury and Osteoarthritis Outcome Score (KOOS) pain, function, and activities of daily living subscales with MACI; trials of other autologous chondrocyte implantation modalities produced mixed results, with 2 trials indicating no difference relative to MF in overall KOOS or other patient-reported outcome measures. One trial indicated significant improvement in overall KOOS relative to MF in a subgroup of patients with symptom onset within 3 years prior to intervention, and 1 trial indicated superior Cincinatti Knee Rating System scores at 10-year follow-up relative to osteochondral autograft transfer.

Abraamyan et al (2022) completed a systematic review with meta-analysis that evaluated cartilage repair techniques, including MF, augmented MF, and autologous chondrocyte implantation/MACI. The authors included a total of 14 RCTs (N=775), and changes from baseline in the 5 KOOS subscales, including KOOS Sport, KOOS Quality of Life, KOOS Symptoms, KOOS Pain, and KOOS Activities of Daily Living, were measured. Only the KOOS Sport subscale demonstrated statistically significant benefits with autologous chondrocyte implantation/MACI procedures compared with MF. The mean delta KOOS Sport after autologous chondrocyte implantation/MACI procedures was 9.9 points greater than after MF and 11.7 points greater than after augmented MF. Comparisons between surgical techniques for the other subscales did not reach statistical significance.

For large lesions, autologous chondrocyte implantation results in better outcomes than MF, particularly in the long term. Studies comparing autologous chondrocyte implantation with osteochondral autograft transfer have shown similar outcomes with smaller lesions, and improved outcomes with autologous chondrocyte implantation when a defect is greater than 4 cm2.

A 2022 systematic review with Bayesian network meta-analysis by Migliorini, Maffulli et al, 2022 evaluated 13 studies with a minimum 18-month follow-up comparing surgical interventions for chondral defects of the talus. The studies comprised 521 patients, with a median follow-up of 47.8 months; most studies, including all that evaluated autologous chondrocyte implantation, were retrospective, with 1 RCT and 2 prospective cohort trials included. The authors found that cell-free autologous membrane-induced chondrogenesis produced the highest American Orthopedic Foot and Ankle Society (AOFAS) scores and produced the lowest rates of failure. However, the timeframe for reporting of AOFAS score and other endpoints was not described, and funnel plots for all reported outcomes suggest the presence of publication bias.

Hu et al (2021) reported a systematic review with meta-analysis of studies published through November 2020. The authors included a total of 23 case series (N=458) with a mean duration of 12 to 154.8 months. In 6 studies, periosteum-covered autologous chondrocyte implantation was applied while 17 studies used second-generation MACI. Results demonstrated an 89% success rate (AOFAS score >80) with autologous chondrocyte implantation. Furthermore, AOFAS scores significantly improved after treatment. Krueger et al (2023) reported a retrospective case series of 36 consecutive patients who underwent autologous chondrocyte implantation for cartilage defects of the acetabulum. With a mean follow-up of 29.9 months (minimum 24 months), the mean modified Harris Hip Score improved significantly between the preoperative baseline and last follow-up, and the mean patient-reported Subjective Hip Value improved from 51.5% at pre-operative baseline to 87.4% postoperatively. The authors stated no serious intraoperative complications or postoperative adverse events were observed.The evidence on the use of autologous chondrocyte implantation for joints other than the knee includes case series, systematic reviews of case series, and a network meta-analysis of prospective and retrospective studies (no prospective studies evaluated autologous chondrocyte implantation). The most commonly reported use of autologous chondrocyte implantation is for the talus; one case series describes use for the acetabulum. Comparative trials are needed to determine whether autologous chondrocyte implantation improves outcomes for lesions of the talus and other joints.

Current research in pig-to-human xenotransplantation includes strategies to overcome the barrier of hyperacute rejection by preventing or inhibiting complement activation caused by Gal- and non-Gal-epitopes. Promising approaches to modulate hyperacute rejection involve gene knockout of GGTA1 and Neu5Gc gene and transgenic expression of hCregs. Chondrocytes from multi-genetically modified pigs might represent a promising cell source for cartilage repair because they are protected from humoral rejection in vitro. While cell viability could be completely preserved with exception of single GalTKO, the residual amount of non-lytic complement activation must be addressed by additional strategies (Tritschler et al, 2021).

POSITION STATEMENT:

Autologous chondrocyte implantation (ACI) with autologous cultured chondrocytes (e.g., Carticel), **OR** matrix-induced chondrocyte implantation (MACI) autologous cultured chondrocytes on porcine collagen membrane (e.g., Vericel) **meets the definition of medical necessity** when **ALL** of the following are met:

- Disabling full thickness articular cartilage defects of the knee caused by acute or repetitive trauma
- Adolescents should be skeletally mature with documented closure of growth plates (eg, ≥15 years)

- Adults should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (eg, < 55 years)
- Focal, full-thickness (grade III or IV) unipolar lesions of the weight-bearing surface of the femoral condyles, trochlea, or patella at least 1.5 cm2 in size
- Documented 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
- Normal knee biomechanics or alignment and stability achieved concurrently with autologous chondrocyte implantation

Autologous chondrocyte implantation (ACI) for all other joints, including but not limited to the shoulder, hip, tibia, ankle, and talus, is considered **experimental or investigational**. There is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes.

*****Outerbridge Arthroscopic Grading System**

Grade 0: Normal cartilage

Grade I: Softening and swelling/blistering

Grade II: Partial thickness defect, fissures < 1.5cm diameter/wide

Grade III: Fissures /defects down to subchondral bone with intact calcified cartilage layer, diameter > 1.5cm

Grade IV: Exposed subchondral bone

BILLING/CODING INFORMATION:

CPT Coding:

27412	Autologous chondrocyte implantation, knee
0737T	Xenograft implantation into the articular surface **(Investigational)**

HCPCS Coding:

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

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Autologous: derived from the implantation recipient.

Chondrocyte: mature cells found in cartilage.

RELATED GUIDELINES:

Unicondylar Interpositional Spacer Devices, 02-2000-26

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/28/25.

GUIDELINE UPDATE INFORMATION:

09/01/01	Coding changes.
01/01/02	Coding changes.
02/15/02	Various revisions.
03/15/03	Reviewed; revised to remove unrelated coding.
08/15/03	Coverage statement for ACI changed; meniscal allograft information removed and separate MCG developed; unrelated coding information removed.
01/01/04	HCPCS coding update.
07/15/04	Review and revision of guideline; consisting of updated references.
01/01/05	Annual HCPCS update; consisting of the addition of 27412 and deletion of S2113.
07/15/05	Review and revision of guideline; consisting of updates references.
09/15/07	Review and revision of guideline consisting of updated references and reformatted guideline.
10/15/09	Scheduled review; no change in position statement.
05/11/14	Revision: Program Exceptions section updated.
03/15/15	Scheduled review. Revised description, position statement, CPT/HCPCS coding, and definitions. Updated references and reformatted guideline.
12/15/15	Revision; updated description section; added coverage for lesions of the patella, and deleted requirement for prior surgical procedure. Added coverage statement (E/I) for juvenile cartilage allografts. Updated index terms and references. Reformatted guideline.
08/15/17	Revision: updated description section. Deleted E/I coverage statement for matrix-induced autologous chondrocyte implantation (MACI). Updated references. Reformatted guideline.
07/15/18	Scheduled review. Revised description section. Revised criteria for autologous chondrocyte implantation. Added Kellgren-Lawrence Grading System. Updated references.
07/15/20	Scheduled review. Revised position statement and updated references.

03/15/22	Scheduled review. Revised description and HCPCS coding. Maintained position statement and updated references.
07/01/22	Quarterly CPT/HCPCS coding update. Added 0737T.
05/23/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.
09/15/24	Scheduled review. Revised description, maintained position statement and updated references.
09/15/25	Scheduled review. Revised description, maintained position statement and updated references.