Autologous Chondrocyte Implantation
SRG-023

Iowa Medicaid Program	Prior Authorization	**Effective Date**	6/1/2023
Revision Number	4	**Last Rev Date**	10/18/2024
Reviewed By	Medicaid Medical Director	**Next Rev Date**	10/17/2025
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	4/15/2022

Descriptive Narrative

Articular cartilage is a highly resilient, viscoelastic material that plays an essential role in reducing stress on subchondral bone and minimizing friction within the joint. Articular cartilage is hyaline cartilage, which consists primarily of matrix, water and only a small number of chondrocytes (cartilage cells). Hyaline cartilage has a low capacity for regeneration because of its avascular and relatively acellular composition.

Autologous chondrocyte implantation (ACI) is performed to treat knee defects caused by damage to the hyaline cartilage. Some of the patient's own cartilage is collected and placed in an ex vivo culture to produce more articular cartilage cells. An initial arthroscopy is done with a biopsy to harvest normal cartilage from a minor load-bearing area within the knee. The chondrocytes are sent to a laboratory where they are isolated from the cartilage matrix and cultured for 3 to 4 weeks to increase the number of viable cells. The cells are returned in suspension for surgical implantation. A knee arthrotomy is performed with any necessary debridement of the surgical field. A periosteal flap graft is next created as a patch. A gel-like medium containing the cultured chondrocytes is placed into the defect area and the periosteal graft is sutured around the periphery to cover the chondrocytes

Chondrocyte grafts may be beneficial for selected patients with severe but limited focal articular cartilage defects. MRI suggests that such chondrocyte grafts achieve a more uniform fill of the chondral defect and are less likely to produce osteophytes than microfracture techniques for promoting cartilage formation. Carefully selected patients may benefit in the short- to medium-term, but more research is needed to establish long-term effectiveness including preventing progression to osteoarthritis.

Nonsurgical treatment options for damage to articular cartilage include weight reduction, physical therapy, braces and orthotics, and non-steroidal anti-

inflammatory agents. A realignment osteotomy (i.e., proximal tibial, distal femoral) is a surgical option to reduce the compressive stress on the damaged articular cartilage in the medial or lateral compartments of the knee. This can be performed instead of, or in addition to ACI. Total joint replacement provides a surgical option but is not advised for younger patients because implants might not withstand the higher levels of physical activity for an extended period.

Classifications of Articular Cartilage Lesions by Severity

Grade	Outerbridge Classification
0	Normal cartilage.
I	Softening and swelling.
II	Fragmentation and fissures in area less than 0.5 inch in diameter.
III	Fragmentation and fissures in area larger than 0.5 inch in diameter.
IV	Exposed subchondral bone.

Modified Classifications of Articular Cartilage Lesions by Severity

Grade	MRI Results	Arthroscopy Results
0	Normal cartilage.	Normal cartilage.
I	Focal areas of hyperintensity with normal contour.	Cartilage with softening and swelling.
II	Blister-like swelling/fraying of articular cartilage extending to surface.	Fragmentation and fissuring within soft areas of articular cartilage.
III	Partial thickness cartilage loss with focal ulceration.	Partial thickness cartilage loss with fibrillation.
IV	Full thickness cartilage loss with underlying bone reactive changes.	Cartilage destruction with exposed subchondral bone.

Kellgren-Lawrence Grading System for Radiographic Assessment of Cartilage Damage

Grade	Description
0	Normal.
1	Doubtful narrowing of joint space and possible osteophytic lipping.
2	Definite osteophytes, definite narrowing of joint space.
3	Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour.
4	Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour.

Modified Outerbridge Grading System for MRI Assessment of Cartilage Damage

Grade	Description
0	Normal.
I	Signal intensity alterations with an intact surface of the articular cartilage compared with the surrounding normal cartilage.
II	Partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter.
III	Fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm.
IV	Exposed subchondral bone head.

Criteria

Prior authorization is required.

ACI is considered medically necessary when **ALL** the following are met:

1. Member is 15 to 55 years of age. For members 15 to 18 years of age, documented skeletal maturity as demonstrated by closure of growth plates by radiography; **AND**
2. BMI ≤35 kg/m^2; **AND**
3. Focal articular cartilage defect down to but not through the subchondral bone (grade III or IV) on a load bearing surface of the femoral condyle (medial, lateral, trochlear) or the patella; **AND**
4. Size of defect is between 1–10 cm^2; **AND**
5. Presence of disabling symptoms such as locking, swelling, or knee pain that limit activities of daily living and symptoms not responsive to conservative therapy for a minimum of 2 months (e.g., medication, physical therapy); **AND**
6. Current normal knee mechanics and alignment are present, or provider plans to concurrently repair during ACI procedure; **AND**
7. Absence of arthritis or degenerative joint disease of the knee.

Investigational – Not Medically Necessary

ACI is considered investigational and not medically necessary when **ANY** of the following are met:

1. Repeat ACI procedure; **OR**
2. Use for the treatment of osteoarthritis or osteochondral dissecans lesions; **OR**
3. Use of non-FDA approved second-generation methods for implanting autologous chondrocytes in a biodegradable matrix and other non-FDA approved products as their effectiveness has not been established; **OR**

4. Use for the treatment of talar lesions of the ankle or lesions of other joints (e.g., hip and shoulder) as the effectiveness of ACI for these lesions has not been established and is not FDA approved.

Coding

The following list(s) of codes are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

CPT/HCPCS	Description
27412	Autologous chondrocyte implantation, knee.
J7330	Autologous cultured chondrocytes, implant.

ICD-10	Description
M17.0-M17.9	Osteoarthritis of knee.
M25.561-M25.569	Pain in knee.
M25.861-M25.869	Other specified joint disorders, knee.
M93.261-M93.269	Osteochondritis dissecans of knee.
M94.9	Disorder of cartilage, unspecified.
S83.30X (A,D,S)-S83.32X(A,D,S)	Tear of articular cartilage of knee, current.

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

Encoder Pro.

Autologous Chondrocyte Implantation, Knee. ACG: A-0415 (AC). Milliman Care Guidelines. Last Update: 9/21/2023.

Joint Surgery 2023-11-05 Clinical Appropriateness Guidelines. Doc ID: MSK02-1123.1. Last review date April 12, 2023.

Matrix-Induced Autologous Chondrocyte Implantation (MACI) Procedure for Repair of articular Cartilage of the Knee. Health Technology Assessment August 26, 2020.

Vericel Corporation web site at https://www.vcel.com/advanced-therapies/#maci.

Mandl LA. Martin GM. Overview of surgical therapy of knee and hip osteoarthritis. UpToDate. Topic last updated: June 07, 2024

National Institute for Health and Care Excellence (NICE). Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee [TA508]. 2018.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version

Signature

Change Date	Changed By	Description of Change	Version
10/18/2024	CAC	Annual Review. References updated.	4

Signature
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Change Date	Changed By	Description of Change	Version
10/20/2023	CAC	Removed Contraindications#5. Removed HCPCS S2112. Updated References.	3

Signature
William (Bill) Jagiello, DO

Criteria Change History

Change Date	Changed By	Description of Change	Version
4/21/2023	CAC	Annual review.	2

Signature
William (Bill) Jagiello, DO

Change Date	Changed By	Description of Change	Version
4/15/2022	CAC	Criteria implementation.	1

Signature
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CAC = Medicaid Clinical Advisory Committee