Description/Summary

A variety of procedures are being developed to resurface articular cartilage defects. Autologous chondrocyte implantation (ACI) involves harvesting chondrocytes from healthy tissue, expanding the cells in vitro, and implanting the expanded cells into the chondral defect. Second- and third-generation techniques include combinations of autologous chondrocytes, scaffolds, and growth factors.

For individuals who have focal articular cartilage lesion(s) of the weight-bearing surface of the femoral condyles, trochlea, or patella who receive ACI, the evidence includes systematic reviews, randomized controlled trials, and prospective observational studies. Relevant outcomes are symptoms, change in disease status, morbid events, functional outcomes, and quality of life. There is a large body of evidence on ACI for the treatment of focal articular cartilage lesions of the knee. For large lesions, ACI results in better outcomes than microfracture, particularly in the long term. In addition, there is a limit to the size of lesions that can be treated with osteochondral autograft transfer, due to a limit on the number of osteochondral cores that can be safely harvested. As a result, ACI has become the established treatment for large articular cartilage lesions in the knee. In 2017, first-generation ACI with a collagen cover was phased out and replaced with an ACI preparation that seeds the chondrocytes onto a bioresorbable collagen sponge. Although the implantation procedure for this second-generation ACI is less technically demanding, studies to date have not shown improved outcomes compared with first-generation ACI. Some evidence has suggested an increase in hypertrophy (overgrowth) of the new implant that may exceed that of the collagen membrane covered implant. Long-term studies with a larger number of patients will be needed to determine whether this hypertrophy impacts graft survival. 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.

For individuals who have focal articular cartilage lesions of joints other than the knee who receive ACI, the evidence includes systematic reviews of case series. Relevant outcomes are symptoms, change in disease status, morbid events, functional outcomes, and quality of life. The greatest amount of literature is for ACI of the talus. Comparative trials are needed to determine whether ACI improves outcomes for lesions in joints other than the knee. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input has been requested on multiple occasions, obtained most recently in 2015, on the use of ACI in the patella. Prior input supported use for localized chondral defects when other treatments have not been successful. The most recent input was generally supportive of the use of ACI for large patellar lesions, although the degree of support varied. Reviewers indicated that outcomes were improved when realignment procedures are performed concurrently with ACI of the patella and that success rates are lower when using ACI after a prior microfracture. Most reviewers recommended that a prior surgical procedure not be required for lesions greater than 4 cm.

**Policy**

**Coding Information**

Click the links below for attachments, coding tables & instructions.

Attachment I- CPT® Code Table & Instructions

**When service or procedure is medically necessary**

Autologous chondrocyte implantation may be considered **medically necessary** for the treatment of disabling full-thickness articular cartilage defects of the knee caused by acute or repetitive trauma when **all** of the following criteria are met:

- Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., ≥15 years). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., <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.
When service or procedure is considered investigational

Autologous chondrocyte implantation for all other joints, including the talar, and any indications other than those listed above is considered investigational.

Policy Guidelines

For smaller lesions (e.g., < 4 cm\(^2\)), if debridement is the only prior surgical treatment, consideration should be given to marrow-stimulating techniques before autologous chondrocyte implantation is performed.

The average defect size reported in the literature is about 5 cm\(^2\); many studies treated lesions as large as 15 cm\(^2\).

Severe obesity (e.g., body mass index (BMI) greater than 35 kg/m\(^2\), may affect outcomes due to the increased stress on weight bearing surfaces of the joint.

Misalignment and instability of the joint are contraindications. Therefore, additional procedures, such as repair of ligaments or tendons or creation of an osteotomy for realignment of the joint, may be performed at the same time. The charges for the culturing component of the procedure are submitted as part of the hospital bill.

The entire matrix-induced autologous chondrocyte implantation (ACI) procedure consists of four steps: 1) the initial arthroscopy and biopsy of normal cartilage, 2) culturing of chondrocytes, 3) a separate arthrotomy to create a periosteal flap and implant the chondrocytes, and 4) post-surgical rehabilitation. The initial arthroscopy may be scheduled as a diagnostic procedure; as part of this procedure, a cartilage defect may be identified, prompting biopsy of normal cartilage in anticipation of a possible chondrocyte transplant. The biopsied material is then sent for culturing and returned to the hospital when the implantation procedure (i.e. arthrotomy) is scheduled.

There is a specific CPT category I code for ACI of the knee: 27412: Autologous chondrocyte implantation, knee

Arthroscopic harvesting of chondrocytes from the knee is reported using CPT code 29870. There is a HCPCS code for the autologous cultured chondrocyte implant - J7330.

Information required

The request must be accompanied by supporting documentation of medical necessity, which includes member’s name and age, symptoms and duration, previous conservative treatments and outcomes, results of prior arthroscopic or surgical repairs including photographs of the defect (may be obtained at time of chondrocyte harvesting), grade level of the defect, size of the cartilage defect, patient’s ability to comply with post-surgical rehabilitation.

Reference Resources

1. Blue Cross and Blue Shield Association Medical Policy MPRM: 7.01.48 - Autologous

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer’s benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member’s health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.

Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group,
benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

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<tr>
<th>Date</th>
<th>Description</th>
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<tr>
<td>04/2010</td>
<td>Updated to mirror BCBSA Medical Policy with slightly less restrictive criteria.</td>
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<tr>
<td>05/2010</td>
<td>Reviewed by CAC</td>
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<tr>
<td>05/2011</td>
<td>Minor updates</td>
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<tr>
<td>02/2014</td>
<td>ICD-10 remediation only, RLG</td>
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<tr>
<td>04/2017</td>
<td>Updated to align with BCBSA MPRM 7.01.48. Updated references. Formatting changes. Removed ICD 9-PCS &amp; ICD10-PCS Tables. Updated ICD 10 table with new codes.</td>
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<td>01/2018</td>
<td>Updated to continue to align with BCBSA MPRM 7.01.48 Matrix-induced ACI removed investigational from policy statement. Removed ICD-10-CM table.</td>
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<td>07/2021</td>
<td>Policy Reviewed. Minor editing to align with BCBSA MPRM Policy 7.01.48. No change to policy intent or benefit.</td>
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<tr>
<td>06/2022</td>
<td>Policy reviewed. Reference updated. No change to policy statement.</td>
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Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors | Date Approved

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

Tom Weigel, MD, MBA
Senior Medical Director
The following codes will be considered as medically necessary when applicable criteria have been met.

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Description</th>
<th>Policy Instructions</th>
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<tbody>
<tr>
<td>CPT®</td>
<td>27412</td>
<td>Autologous chondrocyte implantation, knee</td>
<td>Prior Approval Required</td>
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<tr>
<td>CPT®</td>
<td>27416</td>
<td>Osteochondral autograft(s), knee open (e.g. Mosaicplasty) (Includes harvesting of autograft[s])</td>
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<td>CPT®</td>
<td>29870</td>
<td>Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)</td>
<td>Prior Approval Not Required</td>
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<tr>
<td>HCPCS</td>
<td>J7330</td>
<td>Autologous cultured chondrocytes, implant</td>
<td>Prior Approval Required</td>
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<td>HCPCS</td>
<td>S2112</td>
<td>Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)</td>
<td>Prior Approval Required</td>
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