Medical Policy

**Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions**

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**Policy Number: 374**

BCBSA Reference Number: 7.01.48
NCD/LCD: N/A

**Related Policies**
- Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions, #111
- Meniscal Allograft Transplantation and Collagen Meniscus Implants, #110
- Continuous Passive Motion in the Home Setting, #407
- Orthopedic Applications of Stem Cell Therapy (Including Allograft and Bone Substitute Products Used With Autologous Bone Marrow), #254

**Policy**

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity**

Medicare HMO BlueSM and Medicare PPO BlueSM Members

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 (eg, ≥ 15 years). Adult patients 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 patella¹ or the weight-bearing surface of the femoral condyles or trochlea 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 for all other joints, including talar, and any indications other than those listed above is **INVESTIGATIONAL.**
Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.

Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>Yes</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>Yes</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>Yes</td>
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<tr>
<td>Medicare PPO BlueSM</td>
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</tr>
</tbody>
</table>

CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

### CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>27412</td>
<td>Autologous chondrocyte implantation, knee</td>
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### HCPCS Codes

<table>
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<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>J7330</td>
<td>Autologous cultured chondrocytes, implant</td>
</tr>
<tr>
<td>S2112</td>
<td>Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)</td>
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</tbody>
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### ICD-10-PCS Procedure Codes

<table>
<thead>
<tr>
<th>ICD-10-PCS procedure codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>0SUC07Z</td>
<td>Supplement Right Knee Joint with Autologous Tissue Substitute, Open Approach</td>
</tr>
<tr>
<td>0SUC37Z</td>
<td>Supplement Right Knee Joint with Autologous Tissue Substitute, Percutaneous Approach</td>
</tr>
<tr>
<td>0SUC47Z</td>
<td>Supplement Right Knee Joint with Autologous Tissue Substitute, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0SUD07Z</td>
<td>Supplement Left Knee Joint with Autologous Tissue Substitute, Open Approach</td>
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<tr>
<td>0SUD37Z</td>
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<td>0SUD47Z</td>
<td>Supplement Left Knee Joint with Autologous Tissue Substitute, Percutaneous Endoscopic Approach</td>
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</tbody>
</table>
**Description**

**ARTICULAR CARTILAGE LESIONS**

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 a patient’s activities of daily living and adversely affect quality of life.

**Treatment**

Conventional treatment options include débridement, subchondral drilling, microfracture, and abrasion arthroplasty. Débridement involves the removal of synovial membrane, osteophytes, loose articular debris, and diseased cartilage and is capable of producing symptomatic relief. Subchondral drilling, microfracture, and abrasion arthroplasty attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. Compared with the original hyaline cartilage, fibrocartilage has less capability to withstand shock or shearing force and can degenerate over time, often resulting in the return of clinical symptoms. Osteochondral grafts and autologous chondrocyte implantation (ACI) attempt to regenerate hyaline-like cartilage and thereby restore durable function. Osteochondral grafts for the treatment of articular cartilage defects are discussed in policy #111.

With 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. With the patient 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.

Desired features of articular cartilage repair procedures are the ability (1) to be implanted easily, (2) to reduce surgical morbidity, (3) not to require harvesting of other tissues, (4) to enhance cell proliferation and maturation, (5) to maintain the phenotype, and (6) to integrate with the surrounding articular tissue. In addition to the potential to improve the formation and distribution of hyaline cartilage, use of a scaffold with MACI eliminates the need for harvesting and suture of a periosteal or collagen patch. A scaffold without cells may also support chondrocyte growth.

**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 or trochlea who receive ACI, the evidence includes systematic reviews, randomized controlled trials (RCTs), and prospective observational studies. Relevant outcomes are symptoms, change in disease status, morbidity, and 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 to first-generation ACI. Some evidence has suggested 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 1 RCT and 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. One systematic review found that outcomes following ACI treatment were inferior to microfracture. However, as has been found with cartilage lesions for the knee, marrow stimulation may have a higher failure rate with larger lesions. Comparative trials are needed to determine whether ACI improves outcomes for larger lesions in joints other than the knee. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input was requested on multiple occasions, most recently in 2015, on the use of ACI in the patella. Prior clinical input has supported use for localized chondral defects when other treatments have not been successful. The most recent clinical 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 were performed concurrently with ACI of the patella, and that success rates were lower when using ACI after a prior microfracture. Most reviewers recommended that a prior surgical procedure not be required for lesions greater than 4 cm².

### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>4/2017</td>
<td>Policy statements clarified to include matrix-induced autologous chondrocyte implantation (MACI). 4/1/2017</td>
</tr>
<tr>
<td>1/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>8/2015</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>9/2014</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>7/1/2010</td>
<td>BCBSA National medical policy review. Changes to policy statements.</td>
</tr>
<tr>
<td>1/2010</td>
<td>BCBSA National medical policy review. Changes to policy statements.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


Endnotes

1 Based on expert opinion