

Osteochondral Allografts and Autografts

LOB(s): I Commercial I Medicare	State(s): ⊠ Idaho	🛛 Montana 🖾 Oregon 🖾 Washington 🔲 Other:
🖾 Medicaid	🛛 Oregon	⊠ Washington

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Members with knee cartilage injuries are at risk for future osteoarthritis. There are two primary types of cartilage in the knee: articular (hyaline) cartilage and meniscus (fibrocartilage). The goals of successful cartilage repair include reducing pain, improving long-term function, preventing osteoarthritis subsequent total knee replacements, and rebuilding hyaline cartilage instead of fibrous tissue. Current surgical options for articular cartilage injury include repair (debridement), replacement (osteochondral autograft or allograft transplantation), regeneration (autologous chondrocyte implantation) and meniscal allograft transplantation.

This policy addresses the following types of articular and meniscal replacement surgery

I. Articular cartilage replacement surgery:

- A. Osteochondral Allografting
- B. Osteochondral Autografting (OCG) surgery: OATS and Mosaicplasty
- C. Autologous Chondrocyte Implantation (ACI)
- D. Matrix-Associated Autologous Chondrocyte Implantation (MACI)

II. Meniscal cartilage replacement surgery:

A. Meniscal allograft transplantation

Commercial

Prior authorization is required

I. Articular cartilage replacement surgery:

A. Osteochondral Allografting

PacificSource considers osteochondral allografting to the knee medically necessary when **ALL** of the following criteria is met:

- 1. Member is between age 15 through 55
- 2. Member is skeletally mature
- **3.** The articular cartilage defect is **BOTH**:
 - a. Full-thickness and greater than 2 square centimeters (i.e., length x width)
 - b. Due to trauma or osteochondritis dissecans
- **4.** There is no evidence of degenerative joint disease, inflammatory disease, osteoarthritis, or steroid induced osteonecrosis present in the joint

B. Osteochondral Autografting

PacificSource considers osteochondral autograft transplant (Osteochondral Autograft Transplantation System [OATS] or mosaicplasty) of the knee to be medically necessary when **ALL** of the following criteria are met:

- 1. Member is between age 15 through 55
- 2. Member is skeletally mature
- 3. Repair is for a single articular defect
- 4. The condition involves the weight bearing surface of the femoral condyles or trochlear region
- **5.** The articular chondral defect is full-thickness and less than 2 cm in diameter (i.e., length x width)
- **6.** The member has failed conservative treatment (e.g., medication, physical therapy, and/or arthroscopic repair, such as debridement and/or microfracture)
- **7.** There is no evidence of degenerative joint disease, inflammatory disease, osteoarthritis, or steroid induced osteonecrosis present in the joint

C. Autologous Chondrocyte Implantation (ACI)

PacificSource considers autologous chondrocyte implantation (ACI) to the knee to be medically necessary, when **ALL** of the following criteria is met:

- 1. Member is between age 15 through 55
- 2. Member is skeletally mature
- **3.** Repair is for a single defect
- 4. The defect must be full-thickness, distinct, and unipolar (involving only one side of the joint)

- **5.** Persistent symptoms of disabling localized knee pain for at least 6 months which has failed to respond to conservative treatment (e.g., medication, physical therapy)
- 6. Inadequate response to a prior arthroscopic or other surgical repair procedure
- 7. Meniscus of affected limb is intact
- **8.** There is no evidence of degenerative joint disease, inflammatory disease, osteoarthritis, or steroid induced osteonecrosis present in the joint
- 9. No history of cancer in the bones, cartilage, fat, or muscle of the affected limb
- **10.** The knee is stable with normal alignment (corrective procedure may be performed in combination with or prior to transplantation)
- **11.** Body Mass Index (BMI) less than or equal to 35. CDC link for BMI calculation: <u>http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm</u>.

D. Matrix-Associated Autologous Chondrocyte Implantation (MACI)

PacificSource may consider Matrix-associated autologous chondrocyte implantation (MACI) to the knee to be medically necessary, when **ALL** of the following criteria are met:

- 1. Member is between age 15 through 55
- 2. Member is skeletally mature
- 3. Member is not a candidate for total knee replacement
- 4. Member has focal full-thickness lesions (Grade III or IV) on the weight bearing surface of the femoral condyle (medial, lateral, trochlear or the patella) with absent degenerative changes of the surrounding articular cartilage (Outerbridge Grade II or less) and normal appearing cartilage around the defect
- **5.** The knee is stable with normal alignment (corrective procedure may be performed in combination with or prior to transplantation)
- **6.** The member has failed standard conservative treatment (minimum of 2 months treatment) including medication management and completed course of physical therapy
- 7. Body Mass Index (BMI) less than or equal to 35. CDC link for BMI calculation: http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm.

II. Meniscal cartilage replacement surgery:

A. Meniscal Allograft Transplantation

PacificSource considers Meniscal Allograft Transplantation (MAT) to be medically necessary when **ALL** the following criteria is met:

- 1. Member is younger than 55 years and physically active
- 2. More than half of a meniscus is absent as a result of previous surgery or injury, or a meniscus tear that cannot be repaired
- 3. Persistent activity-related pain
- **4.** The knee is stable with normal alignment (corrective procedure may be performed in combination with or prior to transplantation)
- 5. No or minimal knee osteoarthritis

6. Body Mass Index (BMI) less than or equal to 35. CDC link for BMI calculation: http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm.

Medicaid

PacificSource Community Solutions follows Guideline Note 220 of the OHP Prioritized List of Health Services for coverage of Osteochondral Allografts and Autografts.

PacificSource Community Solutions follows Guideline Note 173 of the OHP Prioritized List of Health Services for coverage of meniscal transplantation and the associated CPT code 29868 to have insufficient evidence of effectiveness.

PacificSource Community Solutions follows Oregon Health Plan (OHP) Diagnostic Procedure Codes, Procedure Group 1119 and does not require prior authorization for code 29870 (Stage I) Arthroscopy, Knee, Dx, W/Wo Synovial Bx.

Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of internal policy guidelines, CMS criteria, and evidence-based criteria, requests are reviewed on an individual basis for determination of coverage and medical necessity. CPT S codes are not covered by Medicare

Experimental/Investigational/Unproven

PacificSource considers the following to be experimental, investigational, or unproven:

- Autologous or allogenic chondrocyte implants of the talus, and patella or any other joint other than the knee
- Collagen Meniscus Implant also known as Bioactive scaffolds (e.g., Menaflex)
- BioCartilage (Arthrex Inc) derived from human cartilage
- Juvenile cartilage allograft tissue implantation (e.g., DeNovo NT Natural Tissue Graft, DeNovo ET Engineered Tissue Graft)
- Meniscal Allograft Transplants (for other indications not listed above)
- Mosaicplasty for any area except the knee
- Osteochondral Autografts treatment to more than one area of the knee and/or more than one plug
- Osteochondral Allografts to any area other than the knee
- Synthetic Matrices for ACI (e.g., BioCart, NeoCart)
- Viable osteochondral allograft (e.g., Cartiform, CartiMax, ProChondrix)

Coding Information

This following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

27412 Autologous chondrocyte implantation, knee

- 27415 Osteochondral allograft, knee, open
- 27416 Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft(s))
- 27599 Unlisted procedure femur
- 28446 Open osteochondral autograft, talus (includes obtaining graft(s)) -
- 29866 Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft(s))
- 29867 Arthroscopy, knee, surgical, osteochondral allograft, (e.g., mosaicplasty)
- 29868 Meniscal transplantation, (includes arthrotomy for meniscal insertion,) medial or lateral
- 29870 Arthroscopy, Knee, Dx, W/Wo Synovial Bx
- 29999 Unlisted procedure, arthroscopy
- J7330 Autologous cultured chondrocytes, implant
- L8699 Prosthetic implant NOS
- S2112 Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)
- G0428 Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)-

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Definitions

- Autologous chondrocyte implantation (ACI) an orthopedic procedure to repair a focal fullthickness cartilage defect on the weight bearing femoral condyles and trochlea of the knee joint, aiming to resurface the joint using the patient's own healthy cartilage cells, harvested arthroscopically from area of healthy cartilage, and grown in a cell culture for 4-5 weeks.
- **Allografting** transplanting a piece of articular cartilage and attached subchondral bone from a cadaver donor to the area that is damaged on the articular surface of a joint.
- **Chondral defect** refers to a focal area of damage to the articular cartilage (the cartilage that lines the end of the bones).
- Matrix-Induced Autologous Chondrocyte Implantation (MACI) a multistage procedure using autologous cultured chondrocytes on porcine collagen membrane.
- **Meniscal Allograft Transplantation (MAT)** considered a salvage procedure, reserved for patients with disabling knee pain following meniscectomy who are considered too young to undergo total knee arthroplasty (TKA).
- **Mosaicplasty** refers to the technique of harvesting small circular (4-8 mm) autogenous grafts from the knee from non-weight bearing regions and transplanting the grafts in a mosaic pattern until the osteochondral defect is filled.
- **Osteochondral Autografts (OATS osteochondral autograft transfer system)** procedure that focuses on single chondral defects where a portion of bone along with articular cartilage is taken and transplanted.

Osteochondral defect - refers to a focal area of damage that involves both the cartilage and a piece of underlying bone.

References

Dekker, T. J., Aman, Z. S., DePhillipo, N. N., Dickens, J. F., Anz, A. W., & LaPrade, R. F. (2021). Chondral Lesions of the Knee: An Evidence-Based Approach. The Journal of bone and joint surgery. American volume, 103(7), 629–645. <u>https://doi.org/10.2106/JBJS.20.01161</u>

Gilat, R., & Cole, B. J. (2020). Meniscal Allograft Transplantation: Indications, Techniques, Outcomes. Arthroscopy : the journal of arthroscopic & related surgery : official publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 36(4), 938–939. <u>https://doi.org/10.1016/j.arthro.2020.01.025</u>

Hayes Knowledge Center, (August 3, 2023) Health Technology Assessment: Matrix-Induced Autologous Chondrocyte Implantation (MACI) Procedure for Repair of Articular Cartilage of the Knee.

Hayes Knowledge Center (August 17, 2022) Health Technology Assessment: Comparative Effectiveness Review Of Stem Cell Therapy For Joint Pain

Hayes Knowledge Center (March 27, 2023) Health Technology Assessment: DeNovo NT Natural Tissue Graft (Zimmer Inc.) for Articular Cartilage Repair of the Knee or Ankle

Kelly, S. R., Stannard, J. T., Reddy, J., Cook, J. L., Stannard, J. P., & Nuelle, C. W. (2023). Meniscus Allograft Transplantation With Bone Plugs Using Knotless All-Suture Anchors and Cortical Button Suspensory Fixation. Arthroscopy techniques, 12(10), e1707–e1714. https://doi.org/10.1016/j.eats.2023.05.020

National Institute for Health and Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee. (2017). *National Institute for Health and Care Excellence*. <u>https://www.nice.org.uk/guidance/ta477/chapter/5-Appraisal-committee-members-and-NICE-project-team</u>

Niemeyer, P., Schubert, T., Grebe, M., & Hoburg, A. (2019). Treatment Costs of Matrix-Associated Autologous Chondrocyte Implantation Compared With Microfracture: Results of a Matched-Pair Claims Data Analysis on the Treatment of Cartilage Knee Defects in Germany. Orthopaedic journal of sports medicine, 7(12), 2325967119886583. <u>https://doi.org/10.1177/2325967119886583</u>

Ozenci, A. M., Gür, S., & Aydin, A. T. (2007). Dizde osteokondral allogreft transplantasyonu [Osteochondral allograft transplantation in the knee]. Acta orthopaedica et traumatologica turcica, 41 Suppl 2, 87–92.

Schrock, J. B., Kraeutler, M. J., Houck, D. A., McQueen, M. B., & McCarty, E. C. (2017). A Cost-Effectiveness Analysis of Surgical Treatment Modalities for Chondral Lesions of the Knee: Microfracture, Osteochondral Autograft Transplantation, and Autologous Chondrocyte Implantation. Orthopaedic journal of sports medicine, 5(5), 2325967117704634. https://doi.org/10.1177/2325967117704634

U.S. Food & Drug Administration. (June 30, 2023). Approved Cellular and Gene Therapy Products. <u>https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products</u>

Vericel. (2020). A Step-By-Step Guide to The MACI Procedure. <u>https://www.maci.com/healthcare-professionals/about-the-procedure/the-maci-procedure.html</u>

Appendix

Policy Number:			
Effective: 4/1/2020	Next review: 3/1/2025		
Policy type: Enterprise			
Author(s):			
Depts: Health Services			
Applicable regulation(s): Guideline Note 173 and Guideline Note 220 of the OHP Prioritized List of Health Services.			
Commercial Ops: 2/2024			
Government Ops: 3/2024			