

Clinical Policy: Articular Cartilage Defect Repairs

Reference Number: NC.CP.MP.26

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Description

Cartilage transfer procedures include autologous chondrocyte implantation, osteochondral allograft transplantation (OAG or OCA) [i.e., including repair of anterior cruciate ligament and meniscus], and osteochondral autograft transplantation [mosaicplasty, Osteochondral Autograft Transplantation System (OATS)]. They are techniques for repairing articular cartilage that has been damaged by trauma or degenerative processes. This policy outlines the medical necessity criteria for each of these procedures.

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® that autologous chondrocyte implantation (ACI) is **medically necessary** when *all* of the following criteria are met:
 - A. Age 18 through 55 years, or documented skeletal maturity if < 18;
 - B. BMI < 35 kg/m²;
 - C. Focal, full-thickness (grade III or IV) articular cartilage defect involving the femoral condyle (medial, lateral, or trochlear) and/or patella;
 - D. Femoral condyle defect size 1 through 10 cm²;
 - E. Disabling symptoms such as locking, swelling, or knee pain that are unresponsive to conservative treatment for a minimum of two months (e.g., medication, physical therapy);
 - F. Previous unsuccessful arthroscopic or surgical revision/repair procedure;
 - G. Knee is stable with intact menisci and ligaments, has normal joint space by X-ray, and is in good alignment (a corrective procedure to stabilize the knee may be performed in combination with or prior to autologous chondrocyte implantation [ACI]);
 - H. Surgery is not intended to treat osteoarthritis of the knee;
 - I. No previous surgery to repair articular cartilage defects with cartilage transfer;
 - J. Member/enrollee is willing and able to comply with prescribed postoperative rehabilitative program;

- II. It is the policy of health plans affiliated with Centene Corporation that osteochondral allograft transplant OR osteochondral autograft transplant of the knee is considered **medically necessary** when *all* of the following criteria are met:
 - A. Age 18 through 55 years, or documented skeletal maturity if < 18;
 - B. BMI < 35 kg/m²;
 - C. Focal, full-thickness (grade III or IV) articular cartilage defect of the lateral or medial femoral condyle, or trochlear region of the knee, and/or patella;
 - D. For osteochondral autograft transplant (e.g., osteochondral autograft transplantation system [OATS]/mosaicplasty), lesion is ≤ 2 cm²; or for osteochondral allograft (OCA) transplant, unipolar lesion that is > 2cm²;

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- E. Disabling symptoms such as locking, swelling, or knee pain unresponsive to conservative treatment for a minimum of two months (e.g., medication, physical therapy);
- F. No evidence of arthritis on the corresponding tibial surface;
- G. Normal appearing hyaline cartilage surrounding the border of the defect, and absent or minimal changes in surrounding articular cartilage;
- H. Normal knee alignment;
- I. Not currently a candidate for total or partial knee replacement.

III. It is the policy of health plans affiliated with Centene Corporation that meniscal allograft transplant is considered **medically necessary** when all of the following criteria are met:

- A. Physically active and physiologically young, under age 55;
- B. Documented mild to moderate articular damage (Outerbridge grade II or less);
- C. Missing > 50% of a meniscus as a result of previous surgery or injury, or a meniscus tear that cannot be repaired;
- D. Disabling knee pain refractory to conservative treatment (e. g., medication, physical therapy);
- E. Normal alignment without varus or valgus deformities;
- F. None of the following contraindications to meniscal allograft transplant:
 - 1. Systemic metabolic degenerative disease (i.e., gout);
 - 2. BMI > 35 kg/m²;
 - 3. Arthritis of the knees or rheumatoid arthritis;
 - 4. Flattening of the femoral condyles or severe degenerative changes (> 50% joint space narrowing, bone on bone, or erosion to subchondral bone);
 - 5. Has undergone partial or total meniscectomy and does not presently have symptoms or problems with their knee.

IV. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of minced articular cartilage repair (allograft or autograft).

V. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of autologous chondrocyte implantation (ACI), osteochondral allograft transplant, or osteochondral autograft transplant for any other indication, or any other joint surface not listed above.

Background

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.^{22,23}

Osteochondral (OC) surfaces that are damaged by trauma or degenerative process usually fill in with fibrocartilage which is less suitable for absorbing stress than is hyaline cartilage. In younger adults, trauma is the most frequent cause of articular cartilage damage. Indications for OC repair include tears, chondral flaps, and loose bodies. All of these defects can result in joint pain, swelling, locking, and giving way.^{22,23}

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Other causes of articular defects include degenerative conditions such as osteonecrosis, osteochondritis dissecans, and osteoarthritis. Osteonecrosis is the death of bone en masse and may arise spontaneously or can result from chronic steroid use. The etiology of this condition is uncertain, although it is thought to result from loss of the blood supply to an area of the subchondral bone. Osteoarthritis, or degenerative arthritis, is the most common form of arthritis in the United States and is characterized by the erosion of articular cartilage.²³

Autologous chondrocyte implantation (ACI) is a two-stage process in which healthy cartilage cells are harvested and cultured and then reimplanted into the defect under a membranous patch at a later date. Allograft transplant involves the transplant of a cadaveric graft consisting of viable articular cartilage and underlying subchondral bone to cover large ($> 2 \text{ cm}^2$), full thickness cartilage defects of the knee. Autograft procedures consist of removing small osteochondral cylinders from low weight-bearing surfaces of the affected joint or another joint in the same patient and inserting them into the affected area to create a mosaic of islands of hyaline cartilage in an area that would otherwise remain without cartilage or fill with only fibrocartilage.^{15,22,23}

Meniscal allograft transplantation is a surgical procedure that involves grafting a donor meniscus into the knee of a recipient. The goal of meniscal transplant surgery is to replace the meniscus cushion before the articular cartilage is damaged. The donor cartilage supports and stabilizes the knee joint, and therefore relieves knee pain.²

Nonsurgical treatment options for damage to articular cartilage include weight reduction, physical therapy, braces and orthotics, intra-articular injection of hyaluronic acid derivatives, 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, a cartilage replacement procedure listed above. Total joint replacement is considered to be “salvage treatment”, especially in patients younger than 55 years.²⁶

The American Academy of Orthopaedic Surgeons (AAOS) believes that for appropriate patients musculoskeletal allografts represent a therapeutic alternative. These tissues should be acquired from facilities that demonstrate compliance, use well-accepted banking methodology, and follow Food and Drug Administration Good Tissue Practices. The AAOS urges all tissue banks to follow rigorous national guidelines and standards and recommends the use of tissue from banks that are accredited by the American Association of Tissue Banks.²

The AAOS has information on meniscal transplant surgery and notes that patient eligibility for this procedure includes missing more than half of a meniscus as a result of previous surgery or injury, or a meniscus tear that cannot be repaired.²

In summary, there have been several randomized controlled studies as well as noncomparative studies that have noted improvement in repairing articular cartilage that has been damaged by trauma or degenerative processes, using the procedures noted within this policy.

Coding Implications

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CPT® Codes	Description
27407	Repair, primary, torn ligament and or capsule of knee; cruciate
27412	Autologous chondrocyte implantation, knee
27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])
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	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral

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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy created and approved	10/08	10/08
Osteochondral implants: added requirement for “absent or minimal changes in surrounding articular cartilage.”	04/18	04/18
In I.A., changed criteria to state age 18 through 55, or documented skeletal maturity if <18, instead of age 15 through 55, or documented skeletal maturity if < 18.	06/18	
References reviewed and updated. Specialist reviewed.	03/19	03/19
References reviewed and updated. Specialist reviewed.	02/20	03/20
Annual review. References reviewed and updated. Replaced “member” with “members/enrollees” in all instances.	01/21	02/21
Annual review. "Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.” “Experimental/investigational” verbiage replaced in criteria IV. And V. with descriptive language. References reviewed, updated, and reformatted. Reviewed by specialist.	02/22	02/22

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Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual review completed. Removed "AND arthroscopic or other repair" from I.E. and added separate criteria I.F. as well as new criteria I.I regarding no previous articular cartilage transfer to treat the defect. Changed "patient" to "member/enrollee" in I.J. Added age and BMI requirements as II.A and B. Updated verbiage in criteria II.D. Added examples to III.D. and BMI criteria to III.F.2. ICD-10 diagnosis code table removed. Background updated with no clinical significance. Dashes removed from ranges. References reviewed and updated. Reviewed by external specialist.	02/23	02/23
CCH policy developed in order to expand medical necessity coverage in criteria I.C. and I.D. adding "and/or patella" to both criteria. Minor rewording with no clinical significance. Coding reviewed and updated. References reviewed and updated. Reviewed by external specialist.	04/24	04/24

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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