

Clinical Policy: Articular Cartilage Defect Repairs

Reference Number: CP.MP.26 Last Review Date: 03/20 Coding Implications Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

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 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);
 - **D.** Femoral condyle defect size $1-10 \text{ cm}^2$;
 - **E.** Disabling symptoms such as locking, swelling, or knee pain that are unresponsive to conservative treatment for a minimum of 2 months (e.g., medication, physical therapy) AND arthroscopic or other surgical repair;
 - **F.** 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]);
 - G. Surgery is not intended to treat osteoarthritis of the knee;
 - **H.** Patient 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.** Focal, full-thickness (grade III or IV) articular cartilage defect of the lateral or medial femoral condyle, or trochlear region of the knee;
 - B. For osteochondral autograft transplant (e.g., OATS/Mosaicplasty), lesion is ≤ 2 cm²; or for osteochondral allograft transplant (e.g., OCA), lesion is > 2cm²;
 - **C.** Disabling symptoms such as locking, swelling, or knee pain that are unresponsive to conservative treatment for a minimum of two months (medication, physical therapy);
 - **D.** No evidence of arthritis on the corresponding tibial surface;
 - **E.** Normal appearing hyaline cartilage surrounding the border of the defect, and absent or minimal changes in surrounding articular cartilage;
 - **F.** Normal knee alignment;



- G. 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. 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. Arthritis of the knees or rheumatoid arthritis;
 - 3. Flattening of the femoral condyles or severe degenerative changes (> 50% joint space narrowing, bone on bone, or erosion to subchondral bone);
 - 4. 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 minced articular cartilage repair (allograft or autograft) is considered investigational because effectiveness has not been established.
- V. It is the policy of health plans affiliated with Centene Corporation that ACI, osteochondral allograft transplant, or osteochondral autograft transplant for any other indication or any other joint surface not listed above is considered **experimental/investigational** because effectiveness has not been established.

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.

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.

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 (NIAMS, 2001; Hangody et al., 2004; Koulalis et al., 2004).

ACI is a two-stage process in which, first, the 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 cm²), full-thickness cartilage defects of the knee. Autograft procedures consist of removing small osteochondral cylinders from low weightbearing 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.

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.

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 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 of time. A 2003 National Institutes of Health (NIH) Consensus Conference advised that other options should be considered for patients under the age of 55 (Hand et al).⁸

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.³

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.³

In summary, there have been a number of 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, through the procedures noted within this policy.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT[®]). CPT[®] is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted



2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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)
29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for
	meniscal), medial or lateral

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

ICD-10-CM Diagnosis Codes that Support Medical Necessity

ICD-10-CM Code	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)-	Tear of articular cartilage of knee, current
S83.32X(A,D,S)	
S89.80X (A,D,S)-	Other specified injuries of lower leg
S89.82X (A,D,S)	

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created and approved	10/08	10/08
Clarified description language	05/14	05/14
Added autologous chondrocyte implantation		
Renamed policy from Mosaicplasty to Articular Cartilage Defect Repairs		
Specialist review - orthopedic		



Reviews, Revisions, and Approvals	Date	Approval Date
Added criteria in which procedures would be considered medically	05/15	05/15
necessary and clarified when and what procedures would not be medically		
necessary		
Specialist review - orthopedic		
Policy converted to new template	05/16	05/16
Added BMI criteria for ACI and age criteria for OAT		
Added criteria for meniscal allograft transplant from the American	08/16	09/16
Academy of Orthopedic Surgeons (2014)		
Added locking and swelling to list of disabling symptoms that could qualify	05/17	05/17
member for procedures in sections I and II. Edited II.B. to correctly label		
mosaicplasty and OATS as autografts, and OCA as an allograft.		
Osteochondral implants: added requirement for "absent or minimal changes	04/18	04/18
in surrounding articular cartilage."		
In I.A., changed criteria to state age 18-55, or documented skeletal maturity	06/18	
if <18 , instead of age 15-55, or documented skeletal maturity if <18 .		
References reviewed and updated. Specialist reviewed.		03/19
References reviewed and updated. Specialist reviewed.	02/20	03/20

References

- 1. American Academy of Orthopaedic Surgeons. 2009 Annual Meeting Podium Presentations. Surgical efficacy of mosaicplasty for capitellar osteochontritis.
- 2. American Academy of Orthopaedic Surgeons. Use of Musculoskeletal Tissue Allografts. Information Statement 1011. 1991. Updated 2001, December 2006, June 2011. Accessed 3/07/2019 at: <u>https://aaos.org/globalassets/about/bylaws-library/information-</u> statements/1011-use-of-musculoskeletal-tissue-allografts.pdf
- 3. American Academy of Orthopedic Surgeons. Meniscal Transplant Surgery. March 2014. Accessed 3/6/2019 at: <u>http://orthoinfo.aaos.org/topic.cfm?topic=a00381</u>
- 4. Chahal J, et al. Outcomes of osteochondral allograft transplantation in the knee. Arthroscopy.2013 Mar;29(3):575-88.
- 5. Chui K, Jeys L, Snow M. Knee salvage procedures: The indications, techniques and outcomes of large osteochondral allografts. World J Orthop. 2015 April 18;6(3):340-350.
- 6. Filardo G, et al. Autologous osteochondral transplantation for the treatment of knee lesion results and limitations at two years' follow-up. Int Orthop. 2013 Mar 25.
- 7. Frank RM, et al. Osteochondral allograft transplantation of the knee: Analysis of failures at 5 years. Am J Sports Med. 2017 Mar; 45(4):864-874. doi: 10.1177/0363546516676072
- 8. Gracitelli GC, Moraes VY, Franciozi CES, Luzo MV, Belloti JC. Surgical interventions (microfracture, drilling, mosaicplasty and allograft transplantation) for treating isolated cartilage defects of the knee in adults (Protocol). Cochrane Database of Systematic Reviews 2016. DOI: 10.1002/14651858.CD010675.pub2.
- 9. Hand CJ, Lobo JJA, White LM, Miniaci A. Osteochondral autograft resurfacing. Sports Medicine & Arthroscopy Review. 2003;11(4):245-263.
- 10. Hangody L, Ráthonyi GK, Duska Z, et al. Autologous osteochondral mosaicplasty surgical technique. J Bone Joint Surg (Am). 2004;86:65-72.





- 11. Hayes. Medical Technology Directory. Comparative Effectiveness Review of First-Generation Autologous Chondrocyte Implantation of the Knee. July 13, 2017. Accessed 2/24/2020.
- 12. Hayes. Medical Technology Directory. Comparative Effectiveness Review of Second- and Third-Generation Autologous Chondrocyte Implantation of the Knee. July 13, 2017. Accessed 2/24/2020.
- 13. Hayes. Health Technology Brief. Osteochondral Allograft Transplantation for Articular Disorders of the Ankle. April 15, 2013. Updated June 26, 2014. Updated May 30, 2015. Archived May 14, 2016.
- 14. Hayes. Medical Technology Directory. Comparative Effectiveness Review of Mosaicplasty for Treatment of Articular Cartilage Injuries. May 4, 2017. Accessed 2/24/2020.
- 15. Hayes. Medical Technology Directory. Meniscal Allograft Transplantation. December 28, 2011. Updated November 5, 2015. Archived Jan 27, 2017.
- 16. Jaiswal PK, et al. The adverse effect of elevated body mass index on outcome after autologous chondrocyte implantation. J Bone Joint Surg. 2012 Oct;94(10):1377-81.
- 17. Lim HC, et al. Current treatments of isolated articular cartilage lesions of the knee achieve similar outcomes. Clin Orthop Relat Res. 2012 Aug;470(8):2261-7.
- 18. Mandl LA, Martin GM. Overview of surgical therapy of knee and hip osteoarthritis. In: UpToDate, Tugwell P (Ed). UpToDate, Waltham, MA. Accessed 02/24/2020.
- 19. Magnussen RA, et al. Treatment of focal articular cartilage defects in the knee, a systematic review. Clin Orthop Relat Res. 2008;466:952-962.
- 20. Mayo Foundation for Medical Education and Research. Advances in articular cartilage defect management. Accessed 02/27/20 at: <u>http://www.mayoclinic.org/medical-professionals/clinical-updates/orthopedic-surgery/innovations-managing-articular-cartilage-defects-knee</u>
- 21. Mistry H, et al. Autologous chondrocyte implantation in the knee: a systematic review and economic evaluation. Health Technol Assess. 2017 Feb;21(6):1-294. doi: 10.3310/hta21060
- 22. National Institute for Health and Clinical Excellence. Mosaicplasty for symptomatic articular cartilage defects of the knee. Interventional Procedure Guidance 607. March 2018. Accessed at: <u>https://www.nice.org.uk/guidance/ipg607</u>
- Ogura T, Mosier BA, Bryant T, Minas T. A 20-Year Follow-up After First-Generation Autologous Chondrocyte Implantation. *Am J Sports Med.* 2017 Oct;45(12):2751-2761. doi: 10.1177/0363546517716631. Epub 2017 Jul 26.
- 24. Nuelle CW, Nuelle JA, Cook JL, Stannard JP. Patient factors, donor age, and graft storage duration affect osteochondral allograft outcomes in knees with or without comorbidities. J Knee Surg. 2017 Feb; 30(2):179-184. doi: 10.1055/s-0036-1584183
- 25. Parkinson B, et al. Factors predicting meniscal allograft transplantation failure. Orthop J Sports Med. 2016 Aug 19; 4(8):2325967116663185. doi: 10.1177/2325967116663185
- 26. Robert H. Chondral repair of the knee joint using mosaicplasty. Review Article. Orthopaedics & Traumatology: Surgery & Research. 2011;97:418-729.
- 27. Vasiliadis HS, Wasiak J. Autologous chondrocyte implantation for full thickness articular cartilage defects of the knee. *Cochrane Database Syst Rev. 2010 Oct* 6;(10):CD003323. *doi:* 10.1002/14651858.CD003323.pub3
- 28. Work Loss Data Institute. Ankle & foot (acute & chronic). Encinitas (CA): Work Loss Data Institute; 2013 Aug 19. Various p.





- 29. Work Loss Data Institute. Knee & leg (acute & chronic). Encinitas (CA): Work Loss Data Institute; 2013 Nov 29. Various p.
- 30. Work Loss Data Institute. Shoulder (acute & chronic). Encinitas (CA): Work Loss Data Institute; 2011. Various p.
- 31. Hayes. Evidence Analysis Research Brief. Hybrid Procedure for Osteochondral Defects of the Knee: Autologous Chondrocyte Implantation (ACI) and Osteochondral Autograft Transfer System (OATS). October 28, 2019.

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.



This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, 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, 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 <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at <u>http://www.cms.gov</u> for additional information.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene[®] and Centene Corporation[®] are registered trademarks exclusively owned by Centene Corporation.