Medical Coverage Policy | Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

EFFECTIVE DATE: 10|01|2016
POLICY LAST UPDATED: 05|05|2021

OVERVIEW

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. This policy addresses autologous chondrocyte implantation (ACI).

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

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 or older). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 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 cm^2 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

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial products and obtained via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Autologous chondrocyte transplantation for the treatment of cartilage defects of the knee is considered medically necessary when medical criteria are met.

Autologous chondrocyte implantation for all other joints, including the talar, and any indications other than those listed above is considered not medically necessary, as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery benefits/coverage.

BACKGROUND

Articular Cartilage Lesions

Bamaged 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 debridement, subchondral drilling, microfracture, and abrasion arthroplasty. Debridement 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 not discussed in this policy.

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 ACI eliminates the need for harvesting and suture of a periosteal or collagen patch. A scaffold without cells may also support chondrocyte growth.

The culturing of chondrocytes is considered by FDA to fall into the category of manipulated autologous structural cells, which are subject to a biologic licensing requirement. In 1997, Carticel® (Genzyme; now Vericel) received FDA approval for the repair of clinically significant, "...symptomatic cartilaginous defects of the femoral condyle (medial lateral or trochlear) caused by acute or repetitive trauma.…"

In December 2016, MACI® (Vericel), received FDA approved for "the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults." MACI® consists of autologous chondrocytes which are cultured onto a bioresorbable porcine-derived collagen membrane. In 2017, production of Carticel® was phased out and MACI® is the only ACI product available in the United States.

The entire matrix-induced ACI procedure consists of 4 steps: (1) initial arthroscopy and biopsy of normal cartilage, (2) culturing of chondrocytes on an absorbable collagen matrix, (3) a separate arthrotomy to place the implant, and (4) postsurgical 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 (ie, arthrotomy) is scheduled.

For individuals who have focal articular cartilage lesions of joints other than the knee who receive ACI, the evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Medicare Advantage Plans and Commercial Products
The following codes are covered when the medical criteria above have been met:

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

HCPCS supply code for the autologous cultured chondrocyte implant:
J7330 Autologous cultured chondrocytes, implant

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, July 2021
Provider Update, July 2020
Provider Update, November 2019
Provider Update, August 2018
Provider Update, September 2017

REFERENCES

1. Blue Cross and Blue Shield Association Technology Evaluation Center. Autologous chondrocyte transplantation. TEC Assessment. 1996;Volume 11:Tab 8.
2. Blue Cross and Blue Shield Association Technology Evaluation Center. Autologous chondrocyte transplantation. TEC Assessment. 1997;Volume 12:Tab 26.
3. Blue Cross and Blue Shield Association Technology Evaluation Center. Autologous chondrocyte transplantation. TEC Assessment. 2000;Volume 15:Tab 12.
4. Blue Cross and Blue Shield Association Technology Evaluation Center. Autologous chondrocyte transplantation of the knee. TEC Assessment. 2003;Volume 18:Tab 2.
5. Niemeyer P, Pestka JM, Kreuz PC, et al. Characteristic complications after autologous chondrocyte implantation for cartilage defects of the knee joint. Am J Sports Med. 2008 Nov;36(11). PMID 18801942
6. Free online Modified Cincinnati Knee Rating System calculator. OrthoToolKit. https://www.orthotoolkit.com/cincinnati/. Accessed February 18, 2020.
7. Greco NJ, Anderson AF, Mann BJ, et al. Responsiveness of the International Knee Documentation Committee Subjective Knee Form in comparison to the Western Ontario and McMaster Universities Osteoarthritis Index, modified Cincinnati Knee Rating System, and Short Form 36 in patients with focal articular cartilage defects. Am J Sports Med. 2010 May;38(5). PMID 20044494
8. Gusi N, Olivares PR, Rajendram R. The EQ-5D Health-Related Quality of Life Questionnaire [Abstract]. In: Preedy VR, Watson RR, eds. Handbook of Disease Burdens and Quality of Life Measures. New York: Springer; 2010:87-89.
9. Roos EM, Engelhart L, Ranstam J, et al. ICRS Recommendation Document: Patient-Reported Outcome Instruments for Use in Patients with Articular Cartilage Defects. Cartilage. 2011 Apr;2(2). PMID 26069575
10. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. Health Qual Life Outcomes. 2003 Nov;1:64. PMID 14613558
11. Collins NJ, Misra D, Felson DT, et al. Measures of knee function: International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford

Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS). Arthritis Care Res (Hoboken). 2011 Nov;63 Suppl 11:S208-28. PMID 22588746
12. Lee WC, Kwan YH, Chong HC, et al. The minimal clinically important difference for Knee Society Clinical Rating System after total knee arthroplasty for primary osteoarthritis. Knee Surg Sports Traumatol Arthrosc. 2017 Nov;25(11). PMID 27324635
13. Clement ND, MacDonald D, Simpson AH. The minimal clinically important difference in the Oxford knee score and Short Form 12 score after total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2014 Aug;22(8). PMID 24253376
14. Copay AG, Eyberg B, Chung AS, et al. Minimum Clinically Important Difference: Current Trends in the Orthopaedic Literature, Part II: Lower Extremity: A Systematic Review. JBJS Rev. 2018 Sep;6(9). PMID 30179898
15. Bin Abd Razak HR, Acharyya S, Tan SM, et al. Predictors of Midterm Outcomes after Medial Unicompartmental Knee Arthroplasty in Asians. Clin Orthop Surg. 2017 Dec;9(4). PMID 29201296
16. Lee WC, Bin Abd Razak HR, Allen JC, et al. Achieving Minimum Clinically Important Difference in Oxford Knee Score and Short Form-36 Physical Component Summary Is Less Likely with Single-Radius Compared with Multiradius Total Knee Arthroplasty in Asians. J Knee Surg. 2019 Mar;32(3). PMID 29635649
17. Riboh JC, Cvetanovich GL, Cole BJ, et al. Comparative efficacy of cartilage repair procedures in the knee: a network meta-analysis. Knee Surg Sports Traumatol Arthrosc. Dec 2017;25(12):3786-3799. PMID 27605128
18. Devitt BM, Bell SW, Webster KE, et al. Surgical treatments of cartilage defects of the knee: Systematic review of randomised controlled trials. Knee. Jun 2017;24(3):508-517. PMID 28189406
19. Mundi R, Bedi A, Chow L, et al. Cartilage restoration of the knee: a systematic review and meta-analysis of level 1 studies. Am J Sports Med. Jul 2016;44(7):1888-1895. PMID 26138733
20. Mistry H, Connock M, Pink J, et al. Autologous chondrocyte implantation in the knee: systematic review and economic evaluation. Health Technol Assess. Feb 2017;21(6):1-294. PMID 28244303
21. Harris JD, Siston RA, Pan X, et al. Autologous chondrocyte implantation: a systematic review. J Bone Joint Surg Am. Sep 15 2010;92(12):2220-2233. PMID 20844166
22. Sacolick DA, Kirven JC, Abouljoud MM, et al. The Treatment of Adult Osteochondritis Dissecans with Autologous Cartilage Implantation: A Systematic Review. J Knee Surg. 2019 Nov;32(11). PMID 30396204
23. Bartlett W, Skinner JA, Gooding CR, et al. Autologous chondrocyte implantation versus matrix-induced autologous chondrocyte implantation for osteochondral defects of the knee: a prospective, randomised study. J Bone Joint Surg Br. May 2005;87(5):640-645. PMID 15855365
24. Saris D, Price A, Widuchowski W, et al. Matrix-applied characterized autologous cultured chondrocytes versus microfracture: two-year follow-up of a prospective randomized trial. Am J Sports Med. Jun 2014;42(6):1384- 1394. PMID 24714783
25. Brittberg M, Recker D, Ilgenfritz J, et al. Matrix-Applied Characterized Autologous Cultured Chondrocytes Versus Microfracture: Five-Year Follow-up of a Prospective Randomized Trial. Am J Sports Med. 2018 May;46(6). PMID 29565642
26. Basad E, Ishaque B, Bachmann G, et al. Matrix-induced autologous chondrocyte implantation versus microfracture in the treatment of cartilage defects of the knee: a 2-year randomised study. Knee Surg Sports Traumatol Arthrosc. Apr 2010;18(4):519-527. PMID 20062969
27. Basad E, Wissing FR, Fehrenbach P, et al. Matrix-induced autologous chondrocyte implantation (MACI) in the knee: clinical outcomes and challenges. Knee Surg Sports Traumatol Arthrosc. Dec 2015;23(12):3729-3735. PMID 25218576
28. Schuette HB, Kraeutler MJ, McCarty EC. Matrix-assisted autologous chondrocyte transplantation in the knee: a systematic review of mid- to long-term clinical outcomes. Orthop J Sports Med. Jun 2017;5(6):2325967117709250. PMID 28620621
29. Meyerkort D, Ebert JR, Ackland TR, et al. Matrix-induced autologous chondrocyte implantation (MACI) for chondral defects in the patellofemoral joint. Knee Surg Sports Traumatol Arthrosc. Oct 2014;22(10):2522-2530. PMID 24817164

30. Zak L, Aldrian S, Wondrasch B, et al. Ability to return to sports 5 years after matrix-associated autologous chondrocyte transplantation in an average population of active patients. Am J Sports Med. Dec 2012;40(12):2815-2821. PMID 23108635
31. Ebert JR, Fallon M, Wood DJ, et al. A prospective clinical and radiological evaluation at 5 years after arthroscopic matrix-induced autologous chondrocyte implantation. Am J Sports Med. Jan 2017;45(1):59-69. PMID 27587741
32. Ebert JR, Fallon M, Zheng MH, et al. A randomized trial comparing accelerated and traditional approaches to postoperative weight-bearing rehabilitation after matrix-induced autologous chondrocyte implantation: findings at 5 years. Am J Sports Med. Jul 2012;40(7):1527-1537. PMID 22539536
33. Ebert JR, Smith A, Edwards PK, et al. Factors predictive of outcome 5 years after matrix-induced autologous chondrocyte implantation in the tibiofemoral joint. Am J Sports Med. Jun 2013;41(6):1245-1254. PMID 23618699
34. Ebert JR, Schneider A, Fallon M, et al. A comparison of 2-year outcomes in patients undergoing tibiofemoral or patellofemoral matrix-induced autologous chondrocyte implantation. Am J Sports Med. Sep 01 2017:363546517724761. PMID 28910133
35. Harris JD, Cavo M, Brophy R, et al. Biological knee reconstruction: a systematic review of combined meniscal allograft transplantation and cartilage repair or restoration. Arthroscopy. Oct 26 2011;27(3):409-418. PMID 21030203
36. Andriolo L, Merli G, Filardo G, et al. Failure of autologous chondrocyte implantation. Sports Med Arthrosc Rev. Mar 2017;25(1):10-18. PMID 28045868
37. Nawaz SZ, Bentley G, Briggs TW, et al. Autologous chondrocyte implantation in the knee: mid-term to long-term results. J Bone Joint Surg Am. May 21 2014;96(10):824-830. PMID 24875023
38. Minas T, Von Keudell A, Bryant T, et al. The John Insall Award: A minimum 10-year outcome study of autologous chondrocyte implantation. Clin Orthop Relat Res. Jan 2014;472(1):41-51. PMID 23979923
39. Minas T, Gomoll AH, Rosenberger R, et al. Increased failure rate of autologous chondrocyte implantation after previous treatment with marrow stimulation techniques. Am J Sports Med. May 2009;37(5):902-908. PMID 19261905
40. Ebert JR, Smith A, Fallon M, et al. Incidence, degree, and development of graft hypertrophy 24 months after matrix-induced autologous chondrocyte implantation: association with clinical outcomes. Am J Sports Med. Sep 2015;43(9):2208-2215. PMID 26163536
41. Shimozono Y, Yasui Y, Ross AW, et al. Scaffolds based therapy for osteochondral lesions of the talus: A systematic review. World J Orthop. Oct 18 2017;8(10):798-808. PMID 29094011
42. Niemeyer P, Salzmann G, Schmal H, et al. Autologous chondrocyte implantation for the treatment of chondral and osteochondral defects of the talus: a meta-analysis of available evidence. Knee Surg Sports Traumatol Arthrosc. Sep 2012;20(9):1696-1703. PMID 22037894
43. American Academy of Orthopaedic Surgeons. Clinical Practice Guideline on the Diagnosis and Treatment of Osteochondritis Dissecans. Rosemont, IL: AAOS; 2010.
44. National Institute for Health and Care Excellence (NICE). Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee [TA508]. 2018; https://www.nice.org.uk/guidance/TA508/chapter/1-Recommendations. Accessed February 20, 2020.