Autologous Chondrocyte Implantation
Clinical Coverage Criteria

Overview

Autologous chondrocyte implantation (ACI) is a well-established two-stage cartilage restoration procedure. The techniques of ACI have evolved over the years, but the principle has remained the same. In December 2016, MACI (Vericel Corporation, Cambridge, MA) received FDA approval 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 that are cultured onto a bioresorbable porcine-derived collagen membrane. In 2017, production of Carticel was phased out, and currently MACI is the only autologous chondrocyte implantation product available in the United States.

MACI is the third and current generation ACI technique with advantages over the second-generation technique. During the first stage the patient's own chondrocytes are harvested from a non-weight bearing area of the knee. The chondrocytes from the cartilage specimen are cultured for approximately 6-8 weeks before being seeded onto a collagen membrane. During the second stage implantation procedure the chondral defect is prepared via arthrotomy with debridement of all damaged cartilage down to but not penetrating the subchondral bone. After measuring the defect, the collage membrane is trimmed to a similar shape and secured to the underlying bone using a layer of fibrin glue. Collagen membrane is characterized by good biocompatibility and complete integration with the adjacent native cartilage. The use of fibrin glue avoids second injury caused by suturing.

FDA approval of MACI was based on results from the SUMMIT Study and the SUMMIT Study Extension. The Summit Study was a two-year prospective, multicenter, randomized, open-label study comparing MACI (n=72) to microfracture (n=72). The results of the SUMMIT Study were published by Saris et al., 2014. The SUMMIT Study (NCT00719576) was conducted at 16 sites across seven countries in Europe from July 2008 to March 2012. SUMMIT enrolled subjects ages 18 to 55 years (mean age 33.8 years and a mean BMI of 26 kg/m^2), with ≥1 symptomatic Outerbridge grade III or IV focal cartilage defect on the medial femoral condyle, lateral femoral condyle, and/or the trochlea at least 3 cm^2 in size and a baseline Knee Injury and Osteoarthritis Outcome Score (KOOS) pain score <55. Exclusion criteria included any knee joint surgery within 6 months prior to screening (not including diagnostic arthroscopy); modified Outerbridge Grade III or IV defect(s) on the patella or tibia; symptomatic musculoskeletal condition in the lower limbs that could impede efficacy measures in the target knee joint; total meniscectomy, meniscal allograft, or bucket handle tear or displaced tear requiring >50% removal of the meniscus in the target knee; malalignment requiring an osteotomy to correct tibial-femoral or patella-femoral alignment; Kellgren-Lawrence grade 3 or 4 osteoarthritis; inflammatory disease or other condition affecting the joints; or septic arthritis within 1 year prior to screening.

At 104 weeks, the improvement with the MACI implant over microfracture in the co-primary endpoint subscores (pain and function) was clinically and statistically significant (p=0.001). The percentage of patients who responded to treatment at 104 weeks, with at least a 10-point improvement from baseline in both KOOS pain and function scores, was significantly greater

(P=0.016) for the MACI group (87.5%) than the microfracture group (68.1%). The number of treatment failures (nonresponders) was 12.5% for MACI vs 31.9% for microfracture (*p*=0.016). MRI evaluation of structural repair was performed in 134 patients at 52 weeks and in 139 patients at 104 weeks. MRI evaluation of structural repair at both time points showed improvement in defect filling for both treatment groups but with no statistically significant differences. Two years after treatment, 83% of patients in the MACI group and 77% of patients in the microfracture group showed a degree of defect fill that was more than 50% of the defect depth. One hundred sixteen patients (MACI implant n=60; microfracture n=56) had a second-look arthroscopy and biopsy. Overall, structural repair tissue was very good; however, the mean microscopic ICRS II overall assessment score between the 2 groups (63.8 versus 62.3) was not significantly different (P=0.717).

Results of the SUMMIT Extension Study were published by Brittberg et al., 2018. The SUMMIT Extension Study (NCT01251588) examined the clinical efficacy and safety results at 5 years. Of the 144 patients randomized in the SUMMIT trial, 65 MACI patients (90.3%) and 63 microfracture patients (87.5%) consented to participate in the SUMMIT Extension study. Sixty-five subjects (65/65) in the MACI group and 59 subjects (59/63) in the microfracture group were available at the 5 year follow-up (total retention = 97%). The mean scores in KOOS pain and KOOS function remained fairly stable for an additional three years in both treatment groups. Five years after treatment, the improvement in MACI over microfracture in the co-primary endpoint of KOOS pain and function was maintained and was clinically and statistically significant (p = 0.022). As in the 2-year SUMMIT results, the MRI evaluation showed improvement in defect filling for both treatments; however, no statistically significant differences were noted between treatment groups.

Until recently, most studies have investigated the use of ACI in the tibiofemoral joint. Early studies reported poor performance in the patellofemoral joint. This may have been due in part to the first and second-generation ACI techniques and because patellofemoral malalignment was often not addressed. In recent years, several small, non-comparative prospective studies have shown encouraging clinical and radiological outcomes in patients undergoing patellofemoral MACI (Gigante et al., 2008, Ebert et al., 2011, Marlovits et al., 2012, Meyerkort et al., 2014, Zhang et al., 2014, Ebert et al., 2015).

In 2017, Ebert and colleagues published results of a study comparing the clinical and radiological outcomes of 127 patients undergoing tibiofemoral MACI to the medial femoral condyle or lateral femoral condyle (n=94 and n=33, respectively) with 67 patients undergoing patellofemoral MACI to the patella (n=35) or trochlea (n=32). No significant differences (p>0.05) were seen in demographics, defect size, prior injury or surgical history, between the two groups. Mean age was 37.7 years and 37.9 years for the tibiofemoral and patellofemoral groups, respectively. Mean defect size was 3.1 cm^2 and 3.0 cm^2 for the tibiofemoral and patellofemoral groups, respectively. Mean BMI was 26.4 and 26.3 for the tibiofemoral and patellofemoral groups, respectively. While the majority of patient-reported outcomes were similar between the two groups pre-surgery, the patellofemoral group did report significantly worse scores for the KOOS ADLs and QOL subscales, which may be partly explained by specific KOOS ADL items more relevant to symptomatic patellofemoral patients, such as descending and ascending stairs, and rising from sitting.

A significant time effect (p<0.05) existed for all patient reported outcome scores throughout the pre- and post-operative timeline. A significant group effect existed for the KOOS subscales of ADL, QOL and Sport in favor of the tibiofemoral group. However, as previously stated patients in the patellofemoral group had significantly lower values at baseline for the KOOS ADLs and QOL sub-scales and overall, actually displayed a similar net improvement over time compared to the tibiofemoral group. Furthermore, despite the significantly worse scores for the KOOS QOL sub-scale in the patellofemoral group, compared with the tibiofemoral group, the largest net improvement over the pre- and post-operative timeline was still noted in the patellofemoral group.

In the 67 patellofemoral patients, there were no significant ($p>0.05$) differences observed in any of the clinical scores, between those who did (n=26), or did not (n=41), undergo concomitant realignment surgery. At 24 months, 90.5% (n=115) of the tibiofemoral group and 83.6% (n=56) of the patellofemoral group were satisfied with the results of their MACI surgery. MRI findings revealed a significant time effect ($p<0.05$) for the MRI composite score, as well as graft infill, signal intensity, subchondral lamina, subchondral bone and joint effusion over the 24 month period. While subchondral lamina scored significantly better in the tibiofemoral group ($p=0.002$), subchondral bone scored significantly better in the patellofemoral group ($p<0.0001$). At 24 months, the overall MRI composite score was classified as Good-Excellent in 98 patients (77%) in the tibiofemoral group and 54 patients (81%) in the patellofemoral group. The degree of graft infill was Good-Excellent in 111 tibiofemoral patients (87%) and 55 patellofemoral patients (82%). At 24 months, 11 tibiofemoral grafts (8.6%) had failed, including 7 on the MFC and 4 on the LFC, as indicated by no discernible tissue on MRI. Only 3 patellofemoral grafts (4.5%) failed, including 2 on the patella and 1 in the trochlea.

A number of early post-operative complications were reported, including wound site opening with or without an associated local infection (tibiofemoral n=3; patellofemoral n=2), deep vein thrombosis (tibiofemoral n=2; patellofemoral n=1) and the development of a post-operative hematoma (tibiofemoral n=1; patellofemoral n=1). these early complications were treated accordingly without further issue. at 24 months post-surgery, a significantly greater ($p<0.001$) percentage of tibiofemoral patients (n=42, 32.1%) displayed hypertrophic grafts on MRI, compared with patellofemoral patients (n=7, 10.4%). At 24 month follow-up, all hypertrophic cases remained asymptomatic clinically, without patient-reported mechanical symptoms or associated pain. At 24 months, 11 tibiofemoral grafts (8.6%) had failed, including 7 on the medial femoral condyle and 4 on the lateral femoral condyle, as indicated by no discernible tissue on MRI. Only 3 patellofemoral grafts (4.5%) had failed, including 2 on the patella and 1 in the trochlea. The authors concluded that MACI in the patellofemoral joint with simultaneous correction of patellofemoral maltracking if required, leads to similarly good clinical and radiological outcomes compared to MACI of the tibiofemoral joint through 24 months post surgery.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial

☒ Medicare Advantage

☒ MassHealth ACO

☒ NaviCare

☐ PACE

Prior authorization is required autologous chondrocyte implantation.

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs)and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have a National Coverage Determination (NCD) for autologous chondrocyte implantation. National Government Services does not have a Local Coverage Determination (LCD) or Local Coverage Article (LCA) for autologous chondrocyte implantation (MCD search 06/15/2021).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. Unless otherwise noted, in the event that there is no Medicare guidance or if the

plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Unless otherwise noted, Fallon Health Clinical Coverage Criteria are used to determine medical necessity for MassHealth ACO-covered services for MassHealth members. Fallon Health Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Fallon Health Clinical Coverage Criteria

Autologous chondrocyte implantation (MACI, Vericel Corporation, Cambridge, MA) is considered medically necessary for the treatment of symptomatic full-thickness focal (unipolar) articular cartilage defects of the knee when all of the follow criteria are met:

1. The plan member is between the ages of 18 and 55 years. If younger than 18 years, the plan member must be skeletally mature with documented closure of growth plates.[1]
2. The size of the defect is >/= 2 cm^2 as documented by arthroscopy or MRI.
3. The lesion is full-thickness (i.e., Outerbridge Grade III or IV) without bone loss.
4. The defect is located on the weight-bearing surface of the medial or lateral femoral condyles, trochlea or patella. Bipolar lesions are a relative contraindication.[2]
5. Patellofemoral malalignment or instability must be addressed with a strategy for correction incorporated into the overall surgical plan.
6. The plan member's BMI is </= 30 kg/m^2 at surgery and this should be maintained postoperatively.[3]
7. Smoking has a deleterious effect in the outcome of ACI.[4] Documentation of non-smoking is required.

Outerbridge Classification System

The characterization of cartilage is as follows:

- Grade 0 - normal cartilage
- Grade I - softening with swelling
- Grade II - a partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm2 in diameter
- Grade III - fissuring to the level of subchondral bone in an area with a diameter of more than 1.5 cm2

[1] The safety and effectiveness of MACI in patients over the age of 55 years has not been established. See Package Insert available at: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/maci-autologous-cultured-chondrocytes-porcine-collagen-membrane.

[2] Yanke AB, Wuerz T, Saltzman BM, Butty D, Cole BJ. Management of patellofemoral chondral injuries. *Clin Sports Med*. 2014 Jul;33(3):477-500.

[3] Mean BMI was 26.2 ± 4.3 kg/m^2 in MACI arm of the SUMMIT Study (NCT00719576), Saris et al., 2014. In a case-controlled study of 60 patients who underwent ACI and 62 who under went MACI, Jaiswal et al. 2012 reported that over the two-year period of follow-up, obese patients (BMI > 30 kg/m^2) did not experience any sustained benefit from ACI or MACI (the mean Modified Cincinnati Score (MCS) preoperatively in the obese group was 33.7; at two-years follow-up the mean MCS score was 30.6).

[4] In a case-controlled study comparing the outcome of ACI in smokers (n=48) and non-smokers (n=66), Jaiswal et al. (2009) found a strong negative correlation between smoking and ACI outcome. At all time intervals after surgery, the proportion of good and excellent results was significantly better in non-smokers compared to smokers. Graft failures were only seen in smokers (p=0.016).

- Grade IV - subchondral bone exposed

Exclusions

- Absolute contraindications for MACI include known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin; severe osteoarthritis, inflammatory arthritis, inflammatory joint disease and uncorrected congenital blood coagulation disorders.
- Plan members who unable to comply with the postoperative rehabilitation and weight-bearing protocol should not be treated with MACI.
- MACI after failed microfracture appears to be associated with a significantly higher failure rate and inferior clinical outcome when compared with MACI as a first-line treatment (Pestka et al., 2018).
- MACI for the treatment of articular cartilage defects on all other joints including but not limited to talus.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
27412	Autologous chondrocyte implantation, knee
J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

References

1. U.S. Food & Drug Administration (FDA). FDA News Release. FDA approves first autologous cellularized scaffold for the repair of cartilage defects of the knee. December 13, 2016. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-autologous-cellularized-scaffold-repair-cartilage-defects-knee.
2. Saris D, Price A, Widuchowski W, Bertrand-Marchand M, et al., SUMMIT study group. Matrix-Applied Characterized Autologous Cultured Chondrocytes Versus Microfracture: Two-Year Follow-up of a Prospective Randomized Trial. *Am J Sports Med*. 2014 Jun;42(6):1384-94.
3. U.S. Food & Drug Administration (FDA). Center for Biologics Evaluation and Research (CBER). Summary Basis for Regulatory Action – MACI. December 13, 2016. Available at: https://wayback.archive-it.org/7993/20190425002036/https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM536121.pdf.
4. Vericel Investor Relations. Press Release. Vericel Initiates Collaboration with Innovative Cellular Therapeutics. Available at: https://investors.vcel.com/node/17006/pdf.
5. Sommerfeldt MF, Magnussen RA, Hewett TE, Kaeding CC, Flanigan DC. Microfracture of Articular Cartilage. *JBJS Rev*. 2016 Jun 28;4(6):01874474-201606000-00006.
6. Na Y, Shi Y, Liu W, Jia Y, Kong L, Zhang T, Han C, Ren Y. Is implantation of autologous chondrocytes superior to microfracture for articular-cartilage defects of the knee? A systematic review of 5-year follow-up data. *Int J Surg*. 2019 Aug;68:56-62.
7. Brittberg M, Recker D, Ilgenfritz J, Saris DBF; SUMMIT Extension Study Group. 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):1343-1351.
8. Steadman JR, Rodkey WG, Briggs KK. Microfracture to treat full-thickness chondral defects: surgical technique, rehabilitation, and outcomes. *J Knee Surg.* 2002;15:170-176.
9. Marlovits S, Aldrian S, Wondrasch B, et al. Clinical and radiological outcomes 5 years after matrix-induced autologous chondrocyte implantation in patients with symptomatic, traumatic chondral defects. *Am J Sports Med*. 2012;40:2273-2280.
10. Mainil-Varlet P, Van Damme B, Nesic D, et al. A new histology scoring system for the assessment of the quality of human cartilage repair: ICRS II. *Am J Sports Med*. 2010 May;38(5):880-90.

11. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes*. 2003 Nov 3;1:64.
12. Ebert JR, Robertson WB, Woodhouse J, et al. Clinical and magnetic resonance imaging-based outcomes to 5 years after matrix-induced autologous chondrocyte implantation to address articular cartilage defects in the knee. *Am J Sports Med*. 2011 Apr;39(4):753-63.
13. Ebert JR, Robertson WB, Lloyd DG, et al. A Prospective, Randomized Comparison of Traditional and Accelerated Approaches to Postoperative Rehabilitation following Autologous Chondrocyte Implantation: 2-Year Clinical Outcomes. *Cartilage*. 2010 Jul;1(3):180-7.
14. 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*. 2012 Jul;40(7):1527-37.
15. Ebert JR, Schneider A, Fallon M, Wood DJ, Janes GC. A Comparison of 2-Year Outcomes in Patients Undergoing Tibiofemoral or Patellofemoral Matrix-Induced Autologous Chondrocyte Implantation. *Am J Sports Med*. 2017 Dec;45(14):3243-3253.
16. Ebert JR, Fallon M, Smith A, Janes GC, Wood DJ. Prospective clinical and radiologic evaluation of patellofemoral matrix-induced autologous chondrocyte implantation. *Am J Sports Med*. 2015 Jun;43(6):1362-72.
17. Brittberg M, Lindahl A, Nilsson A, et al. Treatment of deep cartilage defects in the knee with autologous chondrocyte transplantation. *N Engl J Med*. 1994;331(14):889-895.
18. Niemeyer P, Albrecht D, Andereya S, et al. Autologous chondrocyte implantation (ACI) for cartilage defects of the knee: A guideline by the working group "Clinical Tissue Regeneration" of the German Society of Orthopaedics and Trauma (DGOU). *Knee*. 2016 Jun;23(3):426-35.
19. Niethammer TR, Gallik D, Chevalier Y, et al. Effect of the defect localization and size on the success of third-generation autologous chondrocyte implantation in the knee joint. *Int Orthop*. 2021 Jun;45(6):1483-1491.
20. Gomoll AH, Gillogly SD, Cole BJ, Farr J, Arnold R, Hussey K, Minas T. Autologous chondrocyte implantation in the patella: a multicenter experience. *Am J Sports Med*. 2014 May;42(5):1074-81.
21. Basad E, Ishaque B, Bachmann G, Stürz H, Steinmeyer J. 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*. 2010 Apr;18(4):519-27.
22. 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*. 2013 Jun;41(6):1245-54.
23. Ebert JR, Smith A, Fallon M, Wood DJ, Ackland TR. Correlation Between Clinical and Radiological Outcomes After Matrix-Induced Autologous Chondrocyte Implantation in the Femoral Condyles. *Am J Sports Med*. 2014 Aug;42(8):1857-64.
24. Gigante A, Enea D, Greco F, et al. Distal realignment and patellar autologous chondrocyte implantation: mid-term results in a selected population. *Knee Surg Sports Traumatol Arthrosc*. 2009 Jan;17(1):2-10.
25. Meyerkort D, Ebert JR, Ackland TR, Robertson WB, Fallon M, Zheng MH, Wood DJ. Matrix-induced autologous chondrocyte implantation (MACI) for chondral defects in the patellofemoral joint. *Knee Surg Sports Traumatol Arthrosc*. 2014 Oct;22(10):2522-30.
26. Zhang Z, Zhong X, Ji H, et al. Matrix-induced autologous chondrocyte implantation for the treatment of chondral defects of the knees in Chinese patients. *Drug Des Devel Ther*. 2014 Dec 5;8:2439-48.
27. National Institute for Health and Care Excellence (NICE). Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee [TA477]. October 4, 2017. https://www.nice.org.uk/guidance/ta477.
28. 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.

29. Biant LC, McNicholas MJ, Sprowson AP, Spalding T. The surgical management of symptomatic articular cartilage defects of the knee: Consensus statements from United Kingdom knee surgeons. *Knee*. 2015 Oct;22(5):446-9.
30. Pestka JM, Bode G, Salzmann G, Südkamp NP, Niemeyer P. Clinical outcome of autologous chondrocyte implantation for failed microfracture treatment of full-thickness cartilage defects of the knee joint. *Am J Sports Med*. 2012 Feb;40(2):325-31.
31. Minas T, Gomoll AH, Rosenberger R, Royce RO, Bryant T. Increased failure rate of autologous chondrocyte implantation after previous treatment with marrow stimulation techniques. *Am J Sports Med*. 2009 May;37(5):902-8.
32. Carey JL, Remmers AE, Flanigan DC. Use of MACI (Autologous Cultured Chondrocytes on Porcine Collagen Membrane) in the United States: Preliminary Experience. *Orthop J Sports Med*. 2020 Aug 12;8(8):2325967120941816. 009 May;37(5):902-8.
33. Erggelet C, Vavken P. Microfracture for the treatment of cartilage defects in the knee joint - A golden standard? *J Clin Orthop Trauma*. 2016 Jul-Sep;7(3):145-52.
34. Alford JW and Cole BJ. Chapter 59 Autologous Chondrocyte Implantation. Surgical Techniques in Sports Medicine. *Lippincott Williams & Wilkins*. 1st Ed. 2006.
35. Jaiswal PK, Macmull S, Bentley G, Carrington RW, Skinner JA, Briggs TW. Does smoking influence outcome after autologous chondrocyte implantation?: A case-controlled study. *J Bone Joint Surg Br*. 2009 Dec;91(12):1575-8.
36. Yanke AB, Wuerz T, Saltzman BM, Butty D, Cole BJ. Management of patellofemoral chondral injuries. *Clin Sports Med*. 2014 Jul;33(3):477-500.
37. Jaiswal PK, Bentley G, Carrington RW, Skinner JA, Briggs TW. The adverse effect of elevated body mass index on outcome after autologous chondrocyte implantation. *J Bone Joint Surg Br*. 2012 Oct;94(10):1377-81.
38. Pestka JM, Luu NH, Südkamp NP, et al. Revision Surgery After Cartilage Repair: Data From the German Cartilage Registry (Knorpel Register DGOU). *Orthop J Sports Med*. 2018 Feb 8;6(2):2325967117752623.

Policy history

Origination date:	05/01/2014
Approval(s):	Technology Assessment Committee 12/18/2013 (Adopted InterQual Criteria). 01/28/2015 (annual review), 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review) 1/23/2019 (annual review); 05/27/2020 (Adopted proprietary criteria); 2/23/2021, 6/22/2021 (annual review; added coverage for patella defects; removed requirement for prior surgical repair procedure; added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.