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Surgery of the Knee (for Louisiana Only)

Policy Number: CS068LA.RS
Effective Date: ~~March 1, 2023~~ TBD

[Instructions for Use](#)

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale [MEA2]

Surgery of the knee is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:

- Arthroscopy or Arthroscopically Assisted Surgery, Knee
- Arthroscopy or Arthroscopically Assisted Surgery, Knee (Pediatric)
- Arthroscopy, Diagnostic, +/- Synovial Biopsy, Knee
- Arthrotomy, Knee
- Removal and Replacement, Total Joint Replacement (TJR), Knee
- Total Joint Replacement (TJR), Knee
- Unicondylar or Patellofemoral Knee Replacement

Click [here](#) to view the InterQual® criteria.

Articular cartilage repair is unproven and not medically necessary for treating individuals with any of the following due to insufficient evidence of efficacy:

- Autologous minced or particulated cartilage
- Allogeneic minced or particulated cartilage
- Osteochondral allograft plugs (e.g., Chondrofix)
- Osteochondral discs (e.g., Prochondrix, Cartiform)
- Xenograft implantation into the articular surface of any joint

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Definitions

Allograft Discs (e.g., Cartiform, ProChondrix CR): Wafer-thin Allografts where the bony portion of the Allograft is reduced. The discs contain hyaline cartilage with chondrocytes, growth factors, and extracellular matrix proteins. The graft is often used in conjunction with marrow stimulation purportedly allowing the host mesenchymal stem cells to infiltrate the graft from the underlying bone marrow after stimulation to provide dense extracellular matrix intended to enhance biomechanical stability and promote chondrogenesis (Hayes, 2018; updated 2021).

Allograft Plugs (e.g., Chondrofix): A cylinder-shaped plug (graft) of healthy cartilage tissue and subchondral bone is taken from an area of the bone that does not carry weight (non-weightbearing). The graft is then matched to the surface area of the defect and pushed into place. This leaves a smooth cartilage surface in the joint. (AAOS, 2023).

Minced Cartilage Repair: This procedure uses minced pieces of cartilage seeded over a scaffold which allows for even distribution of the chondrocytes to expand within the defect providing structural and mechanical protection (McCormick et al., 2008).

Xenograft: Graft of tissue taken from a donor of one species and grafted into a recipient of another species.

~~**Knee injury and Osteoarthritis Outcome Score (KOOS):** The KOOS was developed with the purpose of evaluating short-term and long-term symptoms and function in individuals with knee injury and osteoarthritis. The KOOS collects data on five knee-specific patient-centered outcomes: (1) pain; (2) other symptoms such as swelling, restricted range of motion and mechanical symptoms; (3) disability on the level of daily activities; (4) disability on a level physically more demanding than activities of daily living; (5) mental and social aspects such as awareness and lifestyle changes (Roos, 2003; White, 2016).~~

~~**Significant Radiographic Findings:** Kellgren Lawrence classification of osteoarthritis grade 4 large osteophytes, marked joint space narrowing, severe sclerosis, definite bone ends deformity (Kohn, 2016; Dowsey, 2012).~~

~~**Western Ontario and McMaster Universities Arthritis Index (WOMAC):** The WOMAC is a disease-specific, self-administered questionnaire developed to evaluate patients with hip or knee osteoarthritis. It uses a multi-dimensional scale composed of 24 items grouped into three dimensions: pain, stiffness and physical function (White, 2016).~~

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
<u>*0737T</u>	<u>Xenograft implantation into the articular surface</u>
<u>27412</u>	<u>Autologous chondrocyte implantation, knee</u>

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CPT Code	Description
<u>27415</u>	<u>Osteochondral allograft, knee, open</u>
<u>27416</u>	<u>Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])</u>
27437	Arthroplasty, patella; without prosthesis
27438	Arthroplasty, patella; with prosthesis
27440	Arthroplasty, knee, tibial plateau
27441	Arthroplasty, knee, tibial plateau; with debridement and partial synovectomy
27442	Arthroplasty, femoral condyles or tibial plateau(s), knee
27443	Arthroplasty, femoral condyles or tibial plateau(s), knee; with debridement and partial synovectomy
27445	Arthroplasty, knee, hinge prosthesis (e.g., Walldius type)
27446	Arthroplasty, knee, condyle and plateau; medial or lateral compartment
27447	Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)
27486	Revision of total knee arthroplasty, with or without allograft; 1 component
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component
<u>28446</u>	<u>Open osteochondral autograft, talus (includes obtaining graft[s])</u>
<u>29866</u>	<u>Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft[s])</u>
<u>29867</u>	<u>Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)</u>
<u>29868</u>	<u>Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral</u>
29870	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)
29871	Arthroscopy, knee, surgical; for infection, lavage and drainage
29873	Arthroscopy, knee, surgical; with lateral release
29874	Arthroscopy, knee, surgical; for removal of loose body or foreign body (e.g., osteochondritis dissecans fragmentation, chondral fragmentation)
29875	Arthroscopy, knee, surgical; synovectomy, limited (e.g., plica or shelf resection) (separate procedure)
29876	Arthroscopy, knee, surgical; synovectomy, major, two or more compartments (e.g., medial or lateral)
29877	Arthroscopy, knee, surgical; debridement/shaving of articular cartilage (chondroplasty)
<u>29879</u>	<u>Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture</u>
29880	Arthroscopy, knee, surgical; with meniscectomy (medial AND lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed
29881	Arthroscopy, knee, surgical; with meniscectomy (medial OR lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed

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CPT Code	Description
29882	Arthroscopy, knee, surgical; with meniscus repair (medial OR lateral)
29883	Arthroscopy, knee, surgical; with meniscus repair (medial AND lateral)
29884	Arthroscopy, knee, surgical; with lysis of adhesions, with or without manipulation (separate procedure)
29885	Arthroscopy, knee, surgical; drilling for osteochondritis dissecans with bone grafting, with or without internal fixation (including debridement of base of lesion)
29886	Arthroscopy, knee, surgical; drilling for intact osteochondritis dissecans lesion
29887	Arthroscopy, knee, surgical; drilling for intact osteochondritis dissecans lesion with internal fixation
29888	Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction
29889	Arthroscopically aided posterior cruciate ligament repair/augmentation or reconstruction

CPT® is a registered trademark of the American Medical Association

Codes labeled with an asterisk (*) are not on the Louisiana Medicaid Fee Schedule and therefore may not be covered by the state of Louisiana Medicaid Program.

HCPSC Code	Description
<u>*G0428</u>	<u>Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)</u>
<u>*J7330</u>	<u>Autologous cultured chondrocytes, implant</u>
<u>*S2112</u>	<u>Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)</u>

Description of Services

Articular cartilage is a thin layer of specialized connective tissue (hyaline cartilage) that allows for smooth movement, shock absorption, and distribution of load-bearing force in joints. Because it has limited healing capacity, cartilage is susceptible to damage from acute injuries or inflammatory conditions. Cartilage defect symptoms include pain, swelling, and functional disability in the affected joint. Minced cartilage repair is a single staged minimally invasive procedure. This procedure uses minced pieces of cartilage seeded over a scaffold that allows for even distribution of chondrocytes to expand within the defect.

Clinical Evidence

Osteochondral Allograft Discs

The evidence for osteochondral allograft discs consists only of small case series and is insufficient to draw conclusions regarding the effect of this treatment on health outcomes. Further studies with a larger number of patients and longer follow-up are needed, especially larger randomized controlled trials that directly compare osteochondral allograft discs with other established treatments.

Osteochondral Allograft Plug

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The evidence on decellularized osteochondral allograft plugs has reported delamination of the implants and high failure rates. Further studies with a larger number of patients and longer follow-up are needed, especially larger randomized controlled trials that directly compare osteochondral allograft plugs with other established treatments.

Farr et al (2016) reviewed records of an institutional review board-approved database and identified a series of 23 patients with prospectively collected data who had been treated with the implant. Patient-reported outcomes, magnetic resonance imaging (MRI), and the number and type of reoperations were assessed. Failure was defined as structural damage of the graft diagnosed by arthroscopy or MRI, and any reoperation resulting in removal of the allograft. Patients were evaluated pre- and postoperatively using the Knee injury and Osteoarthritis Outcome Score (KOOS) and Marx Sports Activity Scale. MRI was assessed preoperatively and postoperatively. The implant demonstrated a 72% failure rate within the first 2 years of implantation.

Minced Cartilage Repair

Minced cartilage techniques are either not approved in the United States and/or in the early stages of development and testing (e.g., particulated juvenile articular cartilage). Early results from case series appear to show similar outcomes compared with other treatments for cartilage defects, but these case series do not allow conclusions regarding the effect of this treatment on health outcomes. The case series have suggested an improvement in outcomes compared with baseline, but there is also evidence of subchondral edema, nonuniform chondral surface, graft hypertrophy, and delamination. Further studies, preferably from larger randomized controlled trials (RCTs) that directly compare particulated juvenile articular cartilage with other established treatments and the effect on health outcomes compared with other available procedures. Runer & Salzmann (2022) reviewed the current evidence supporting chondrocyte-based, single-stage cartilage repair, focusing on the autologous minced cartilage implantation technique. The authors uncovered limited evidence; for example, only in vitro and animal studies showed that the induction of de novo production of extracellular matrix, chondrocyte outgrowth, proliferation, and differentiation has encouraged tissue generation. The authors concluded from the available in vitro and in vivo data autologous minced cartilage repair is a promising single-stage cartilage repair procedure with robust biological, economic, and clinical potential. However, high-level, long-term, comparative clinical trials with larger cohorts are needed to compare with other cartilage repair techniques and determine implant efficacy.

Hayes reviewed literature for DeNovo NT Natural Tissue Graft for Articular Cartilage Repair of the Knee or Ankle in a Health Technology Assessment. The authors concluded that there was very-low-quality body of evidence. The assessment uncovered small, poor- to very-poor-quality studies and is insufficient to draw conclusions on the balance of benefits and harms associated with DeNovo NT for articular cartilage repair (Hayes, 2019; updated 2021).

Xenografts

Xenografts for repair of cartilage defects is being studied by some investigators as an alternative to autografts and allografts. Decellularization processes are in the early stages of investigation in order to remove antigens from the graft, which in theory would reduce rejection. Once decellularization methods are established, additional studies will be necessary to establish evidence of safety and efficacy.

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U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Surgeries of the knee are procedures and therefore not regulated by the FDA. However, devices and instruments used during the surgery require FDA approval. Refer to the following website for additional information:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed ~~August 15~~ **July 14**, 2023~~2~~)

Transplantation of meniscal allografts and osteochondral autografts is a surgical procedure and, as such, is not subject to regulation by the FDA. However, the FDA does regulate certain aspects of tissue banking, and tissues are subject to FDA registration and requirements for good tissue practices and infectious disease screening and testing, as well as to the good manufacturing practice requirements applicable to drugs and devices. According to current rules, FDA premarket review or marketing approval is not required for minimally processed tissues transplanted from one person to another for their normal structural functions; these criteria apply to meniscal allografts. Refer to the following website for more information:

<http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm>. (Accessed May 10, 2023)

Collagen meniscus implants, also known as collagen scaffold, are bioresorbable, primarily bovine type 1 collagen products that are designed as a tissue-engineered scaffold to support the generation of new meniscus-like tissue. For information on collagen meniscus implants, refer to the following FDA website for Premarket Approvals (use product code OLC): <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> (Accessed May 10, 2023)

Refer to the following website for more information regarding products used for Autologous Chondrocyte Transplantation and search by product name in device name section: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed May 17, 2023)

Donor tissue products derived from human cartilage, such as the DeNovo NT tissue graft, are regulated under the guidelines for Human Cell, Tissues and Cellular and Tissue-Based Products (HCT/P) issued by the Center for Biologics Evaluation and Research (CBER) of the FDA. The CBER does not regulate the transplantation of these products per se, but it does require tissue establishments to register with the FDA in the Establishment Registration & Device Listing database. As part of the FDA regulations, tissue establishments must screen and test donors, to prepare and follow written procedures for the prevention of the spread of communicable disease, and to maintain records.

References

Academy of Orthopaedic Surgeons (AAOS). OrthInfo: Articular Cartilage Restoration. 2023. Available at: <https://orthoinfo.aaos.org/en/treatment/articular-cartilage-restoration/>. Accessed May 11, 2023.

Farr J, Gracitelli GC, Shah N, et al. High failure rate of a decellularized osteochondral allograft for the treatment of cartilage lesions. Am J Sports Med. Aug 2016;44(8):2015-2022.

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Hayes Inc, Hayes Health Technology Assessment. DeNovo NT Natural Tissue Graft (Zimmer Inc.) for Articular Cartilage Repair of the Knee or Ankle. Lansdale, PA: Hayes, Inc., December 2019; updated December 2021.

McCormick F, Yanke A, Provencher MT, et. al. Minced articular cartilage-basic science, surgical technique, and clinical application. Sports Med Arthrosc Rev. 2008 Dec;16(4):217-20.

Runer, A., & Salzman, G. M. (2022). Moving towards single stage cartilage repair --- is there evidence for the minced cartilage procedure? Journal of Cartilage & Joint Preservation, 2 (2),100053.

Bellamy N, Buchanan WW, Goldsmith CH, et al. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. J Rheumatol. 1988 Dec;15(12):1833-40.

Dowsey MM, Nikpour M, Dieppe P, Choong PF. Associations between pre-operative radiographic changes and outcomes after total knee joint replacement for osteoarthritis. Osteoarthritis Cartilage. 2012 Oct;20(10):1095-102.

Kohn MD, Sassoan AA, Fernando ND. Classifications in brief: Kellgren-Lawrence classification of osteoarthritis. Clin Orthop Relat Res. 2016 Aug;474(8):1886-93.

Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. Health Qual Life Outcomes. 2003;1:64. Published 2003 Nov 3.

Roos EM, Roos HP, Lohmander LS, et al. Knee Injury and Osteoarthritis Outcome Score (KOOS)--development of a self-administered outcome measure. J Orthop Sports Phys Ther. 1998 Aug;28(2):88-96.

White DK, Master H. Patient-reported measures of physical function in knee osteoarthritis. Rheum Dis Clin North Am. 2016;42(2):239-252.

Policy History/Revision Information

Date	Summary of Changes
<u>TBD</u>	<p><u>Template Update</u></p> <ul style="list-style-type: none"><u>Reorganized and combined content previously included in the Medical Policies titled:</u><ul style="list-style-type: none"><u>Articular Cartilage Defect Repairs (for Louisiana Only)</u><u>Meniscus Implant and Allograft (for Louisiana Only)</u><u>Surgery of the Knee (for Louisiana Only)</u> <p><u>Coverage Rationale</u></p> <ul style="list-style-type: none"><u>Revised language to indicate:</u><ul style="list-style-type: none"><u>Surgery of the knee is proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:</u><ul style="list-style-type: none"><u>Arthroscopy or Arthroscopically Assisted Surgery, Knee</u><u>Arthroscopy or Arthroscopically Assisted Surgery, Knee (Pediatric)</u><u>Arthroscopy, Diagnostic, +/- Synovial Biopsy, Knee</u><u>Arthrotomy, Knee</u>

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- Removal and Replacement, Total Joint Replacement (TJR), Knee
- Total Joint Replacement (TJR), Knee
- Unicondylar or Patellofemoral Knee Replacement
- Articular cartilage repair is unproven and not medically necessary for treating individuals with any of the following due to insufficient evidence of efficacy:
 - Autologous minced or particulated cartilage
 - Allogeneic minced or particulated cartilage
 - Osteochondral allograft plugs (e.g., Chondrofix)
 - Osteochondral discs (e.g., Prochondrix, Cartiform)
 - Xenograft implantation into the articular surface of any joint

Definitions

- Added definition of:
 - Allograft Plugs (e.g., Chondrofix)
- Removed definition of:
 - Allograft
 - Allografts
 - Autografts
 - Autologous Chondrocyte Transplantation (ACT)
 - Collagen Meniscal Implant (CMI)
 - Femoral Condyles
 - Focal Defect
 - Functional or Physical Impairment
 - Juvenile Cartilage Allograft Tissue Implantation (e.g., DeNovo® NT Natural Tissue Graft)
 - Knee injury and Osteoarthritis Outcome Score (KOOS)
 - Matrix-Induced Autologous Chondrocyte Implantation (MACI) Procedure
 - Meniscal Allograft Transplantation (MAT)
 - Microfracture
 - Mosaicoplasty
 - Osteochondral Allograft (OCA)
 - Osteochondral Autologous Transplant (OAT)
 - Osteochondral Autograft Transfer System (OATS)
 - Outerbridge Classification of Articular Lesions by Severity
 - Significant Radiographic Findings
 - Western Ontario and McMaster Universities Arthritis Index (WOMAC)

Applicable Codes

- Removed notation indicating HCPCS code G0428 are not on the State of Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program

Supporting Information

- Updated Description of Services, Clinical Evidence, FDA, and References sections to reflect the most current information
- Archived previous policy version CS068LA.R

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