Surgery of the Knee

Guideline Number: MMG072.U
Effective Date: October 1, 2023

Instructions for Use

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Related Medical Management Guideline

- Unicondylar Spacer Devices for Treatment of Pain or Disability

Coverage Rationale

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

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

Required Clinical Information
Surgery of the Knee

Medical notes documenting the following, when applicable:

- Upon request, we may require the specific diagnostic image(s) that show the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal images
  - **Note**: When requested, diagnostic image(s) must be labeled with:
    - The date taken
    - Applicable case number obtained at time of notification, or member's name and ID number on the image(s)
  - Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted
- Complete report(s) of diagnostic imaging (MRI, CT scan, X-rays, and bone scan), including:
  - Documented closure of skeletal plates (age less than 18 years)
  - Presence or absence of focal full-thickness articular cartilage defect
  - Size and location of focal cartilage defect
  - Outerbridge grade
  - Joint space and alignment
- Reports of all recent applicable diagnostic tests, including:
  - Microbiological findings
  - Synovial exam
  - Erythrocyte sedimentation rate (ESR)
  - C-reactive protein (CRP)
- Condition requiring procedure
- Symptoms
- Severity of pain and details of functional disability(ies) interfering with activities of daily living (ADL) (preparing meals, dressing, driving, walking)
- Cause of defect (e.g., acute or repetitive trauma)
- Pertinent physical examination of the relevant joint
- Consideration of arthroscopic approach
- Co-morbid medical condition(s)
- Prior therapies/treatments tried, failed, or contraindicated; include the dates, duration, and reason for discontinuation
- Date of failed previous surgery to the same joint (proximal tibial or distal femoral osteotomy, if applicable)
- Physician's treatment plan, including pre-op discussion
- For revision surgery, also include:
  - Details of complication
  - Complete (staged) surgical plan
- If the location is being requested as an inpatient stay, provide medical notes to support the following, when applicable:
  - Surgery is bilateral
  - Member has significant co-morbidities; include the list of comorbidities and current treatment
  - Member does not have appropriate resources to support post- operative care after an outpatient procedure; include the barriers to care as an outpatient

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.

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 guideline 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 the member specific benefit plan document 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
0737T	Xenograft implantation into the articular surface
27412	Autologous chondrocyte implantation, knee
27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])
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
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
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)
29879	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture

CPT Code	Description
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
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

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

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 singlestaged 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

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.

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 May 17, 2023)

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.

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., & Salzmann, 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.

Guideline History/Revision Information

Date	Summary of Changes

10/01/2023	**Template Update**
	• Reorganized and combined content previously included in the Medical Policies titled:
	  ○ *Articular Cartilage Defect Repairs*
	  ○ *Meniscus Implant and Allograft*
	  ○ *Surgery of the Knee*
	Coverage Rationale
	• Revised language to indicate:
	  ○ 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
	  ○ 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
	Documentation Requirements
	• Updated list of *Required Clinical Information*:

Date	Summary of Changes
	○ Added: ▪ Complete report(s) of diagnostic imaging (MRI, CT scan, X-rays, and bone scan), including: – Documented closure of skeletal plates (age less than 18 years) – Presence or absence of focal full-thickness articular cartilage defect – Size and location of focal cartilage defect ▪ Symptoms ▪ Cause of defect (e.g., acute or repetitive trauma) ○ Removed "documented closure of skeletal plates (pediatric patients)" ○ Replaced: ▪ "Reports of all recent *imaging studies and* applicable diagnostic tests" with "reports of all recent applicable diagnostic tests" ▪ "Severity of pain and details of functional disability(ies) interfering with activities of daily living (preparing meals, dressing, driving, walking) *using a standard scale, such as the Western Ontario and McMaster Universities Arthritis Index (WOMAC) or the Knee injury and Osteoarthritis Outcome Score (KOOS)*" with "severity of pain and details of functional disability(ies) interfering with activities of daily living (preparing meals, dressing, driving, walking)" ▪ "Prior therapies/treatments tried, failed, or contraindicated; include the dates and reason for discontinuation" with "prior therapies/treatments tried, failed, or contraindicated; include the dates, *duration*, and reason for discontinuation" **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 ○ Mosacicplasty ○ 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) **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy versions MMG006.Q, MMG083.M, and MMG072.T

Instructions for Use

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific

benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare West Medical Management Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.