

Surgery of the Knee (for Pennsylvania Only)

Policy Number: CS068PA.Z
Effective Date: April 1, 2026

[Instructions for Use](#)

Table of Contents	Page
Application	1
Coverage Rationale	1
Medical Records Documentation Used for Reviews	2
Definitions	2
Applicable Codes	4
Description of Services	5
Clinical Evidence	5
U.S. Food and Drug Administration	8
References	8
Policy History/Revision Information	9
Instructions for Use	9

Related Policies
None

Application

This Medical Policy only applies to the state of Pennsylvania. Any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis. Refer to [Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101](#).

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
- Arthrotomy, Knee (Pediatric)
- 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 [e.g., Cartilage Autograft Implantation System (CAIS), Reveille Cartilage Processor]
- Allogeneic minced or particulated cartilage [e.g., BioCartilage®, DeNovo Natural Tissue (NT) Graft, Denovo ET]
- Collagen Meniscus Implant
- Decellularized Osteochondral Allografts (e.g., Chondrofix)
- Reduced osteochondral discs (e.g., Prochondrix, Cartiform)
- Synthetic Resorbable Polymers [e.g., PolyGraft BGS, TruFit (cylindrical plug), TruGraft (granules)]
- Xenograft implantation

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

Medical notes documenting the following, when applicable:

- Complete diagnostic interpretation of imaging findings including, at a minimum:
 - Relevant clinical information
 - Detailed report of imaging findings, including at least the following:
 - 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
 - Ligament tear location and grade
 - Impression
 - Specialty(ies) of the provider(s) who interpreted the images
- In addition, 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 image(s) must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted
- 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
- Cause of defect (e.g., acute or repetitive trauma)
- Pertinent physical examination of the relevant joint
- 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, if applicable
- Physician's treatment plan including:
 - Pre-op discussion
 - Additional intervention(s) or product(s) to be used during the procedure
- Consideration of arthroscopic approach, if applicable
- For revision surgery, also include:
 - Details of complication
 - Complete (staged) surgical plan
- If the location being requested is an inpatient stay, provide medical notes to support at least one of the following:
 - 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

BioCartilage®: Dehydrated, micronized allograft articular cartilage matrix that is intended to provide a scaffold for microfracture. The small particles are mixed with a blood solution to create a paste-like consistency that is applied over a cartilage defect (Hayes, 2022).

Cartilage Autograft Implantation System (CAIS): Harvests minced autograft cartilage and disperses chondrocytes on a scaffold in a single-stage treatment (Farr et al., 2012).

Collagen Meniscus Implants: Collagen implants are also known as collagen scaffolds, are implantable porous meniscus scaffolds composed of collagen fibers, enriched with glycosaminoglycan, used as a template and support for generation of new tissue to replace the lost menisci (AAOS, 2023).

Decellularized Osteochondral 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-weight bearing). 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).

DeNovo ET (Engineered Tissue) Graft: An in vitro grown, 3-dimensional hyaline-like cartilage tissue created by culturing disaggregated allogeneic chondrocytes derived from juvenile human donors (Farr et al., 2012).

DeNovo NT (Natural Tissue) Graft: DeNovo NT consists of manually particulated cartilage obtained from juvenile allograft donor joints. The tissue fragments are mixed intraoperatively with fibrin glue before implantation in the prepared lesion (Farr et al., 2012).

Disabling Pain: Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain domain > 40 (Quintana, 2009).

Functional Disability: Western Ontario and McMaster Universities Arthritis Index (WOMAC) functional limitation domain > 40 (Quintana, 2009).

Minced Cartilage: A procedure that 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).

Outerbridge Grades:

- Grade 0: Normal
 - Grade I: Cartilage with softening and swelling
 - Grade II: Partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter
 - Grade III: Fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm
 - Grade IV: Exposed subchondral bone head
- (Slattery, 2018)

Reduced Allograft Discs [e.g., Cartiform (Arthrex), ProChondrix CR (Allosource)]: 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).

Reveille Cartilage Processor: High-speed blade and sieve to cut autologous Minced Cartilage into small particles for implantation (Igarashi et al., 2020).

Radiographic Findings of Osteoarthritis: Narrowing of joint space, osteophyte formation, subchondral sclerosis, subchondral cysts, deformity of bony end-plates, and thinning or complete loss of articular cartilage (ACR, 2025).

Note: United Healthcare will accept three or more moderate to severe radiographic findings to be sufficient to support the diagnosis of severe osteoarthritis.

Synthetic Resorbable Polymers: Implant that functions as a scaffold for chondral and osteogenic cells with the synthetic polymer being resorbed as the cells produce their normal matrices (AAOS, 2023).

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 (Quintana, 2009).

Xenograft: Graft of tissue taken from a donor of one species and grafted into a recipient of another species (AAOS, 2023).

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
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])
27418	Anterior tibial tubercleplasty (e.g., Maquet type procedure)
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
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
27658	Repair, flexor tendon, leg; primary, without graft, each tendon
27659	Repair, flexor tendon, leg; secondary, with or without graft, each tendon
27664	Repair, extensor tendon, leg; primary, without graft, each tendon
27665	Repair, extensor tendon, leg; secondary, with or without graft, each tendon
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, 2 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

CPT® is a registered trademark of the American Medical Association

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. Autologous or allogeneic Minced Cartilage, Decellularized Osteochondral Allograft Plugs, Synthetic Resorbable Polymers, collagen implants, and reduced osteochondral allograft discs are being evaluated as a treatment of articular cartilage lesions.

Clinical Evidence

Autologous or Allogenic Minced or Particulated Cartilage

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 the 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 performed evidence analysis research brief for Extracellular Matrix with BioCartilage for Orthopedic Indications. A review of abstracts suggests that there currently is not enough published peer-reviewed literature to evaluate the evidence related to BioCartilage for orthopedic indications in a full assessment. (Hayes, 2022).

In a Health Technology Assessment Product Brief published by ECRI (2019), the evidence for BioCartilage Extracellular Matrix for Repairing Cartilage Defects in the Knee was inconclusive. The only identified evidence that reported on any clinical outcomes of BioCartilage is a review of an unspecified number of case studies on BioCartilage's clinical performance, which reported very limited outcomes. These case studies are at high risk of bias because of lack of a control group and randomization, and although the abstract does not report the number of case studies. Randomized controlled trials with a sufficient sample size are needed to compare microfracture surgery with and without use of BioCartilage and determine whether its use improves clinical outcomes.

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).

Collagen Meniscus Implant (CMI)

There is insufficient evidence to demonstrate the efficacy of collagen meniscus implants for treating meniscus injuries or tears. Robust randomized controlled trials are needed along with long-term outcomes to establish the safety and efficacy of this procedure.

Kohli et al. (2022) performed a systematic review comparing clinical outcomes and failure rates of patients who have had implantation with meniscal scaffolds. The authors concluded that the evidence for meniscal scaffold use is insufficient to suggest that they could potentially improve clinical outcomes in patients following meniscal resection. This was largely due to the high proportion of concurrent procedures carried out at index procedure for collagen meniscal implant (CMI). These investigators stated that on the basis of current evidence, the use of meniscal scaffolds as a sole treatment for partial meniscal defects could not be recommended, owing to the relatively high failure rate and paucity of clinical data. They noted that the evidence for their chondro-protective effects, and thus prevention of secondary osteoarthritis, remains inconclusive. First, there was a high volume of concurrent procedures carried out at the time of meniscal implantation. Second, there was also a significant variability in the clinical outcomes reported. These factors made direct meaningful comparison of clinical outcomes impossible. Third, the inclusion criteria for the individual studies included in this review also varied. Given the high level of heterogeneity, meta-analyses and statistical comparison were felt not to be appropriate at this stage. These researchers stated that further high-quality comparative RCTs are needed before meniscal scaffolds can be recommended for routine clinical use.

Lucidi et al. (2022) performed a retrospective, case-control, single-center study. They examined the factors that predict failure of meniscal scaffold implantation to better define the indications for surgery. The analysis included 186 consecutive patients with a minimum 5-year follow-up who underwent CMI scaffold implantation or combined procedures. Patients with a Lysholm score of less than 65 were considered to have experienced clinical failure. Surgical failure was defined as partial or total scaffold removal. The authors concluded that CMI for partial meniscal deficiency provided good long-term results, with 87.8% of the implants still in-situ at a mean 10.9 years of follow-up. The authors noted that this study had several limitations including retrospective study, lack of a control group, as well as MRI was not carried out at the last follow-up; thus, it was impossible to prove whether the scaffold implant could provide a real benefit in terms of chondro-protection or symptom relief compared with isolated meniscectomy. It was not possible to analyze whether the location of the meniscal lesion, the degree of meniscectomy, and the size of the CMI were risk factors for failure. And finally, there was a considerable percentage of patients who underwent an associated surgical procedure during the CMI surgery.

Grassi et al. (2021) assessed the clinical outcomes and failures of lateral CMI implantation at a minimum 10-year follow-up. This study included 24 consecutive patients who underwent lateral CMI implantation for partial lateral meniscal defects and who were part of a previous study with a 2-year follow-up. Outcome measures at the latest follow-up included the Lysholm score, Knee injury and Osteoarthritis Outcome Score, visual analog scale (VAS) for pain, Tegner activity level, and EuroQol 5-Dimensions score. The authors concluded that lateral CMI implantation for partial lateral meniscal defects provided good long-term results, with a 10-year survival rate of 85% and a 14-year survival rate of 64%. At the final follow-up, 58% of the patients had "good" or "excellent" Lysholm scores. However, there was a general decrease in outcome scores between the short- and the long-term follow-up. According to the authors, although this represents the first study to assess the long-term outcome of lateral meniscal replacement using a scaffold, several limitations are present. Including limited number of patients, which did not allow the performance of sophisticated statistical sub analyses to identify outcomes and failure predictors. According to the authors, additional factors such as a surgical learning curve, the time

from meniscectomy to scaffold implantation and the cartilage status, and the time of the index surgery could be relevant and should be investigated in studies with a larger sample size.

Decellularized Osteochondral Allografts

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.

Johnson et al. (2017) published the results of a case series that evaluated the short-term clinical and radiographic outcomes following the use of decellularized osteochondral (OC) allograft plugs in the treatment of distal femoral OC lesions, including 34 patients. Patient-reported outcomes along with MRI results were recorded at 6 months, 1 year, and 2 years by independent observers. At a mean follow-up of 15.5 months (range, 6- 24), 10 (29%) patients required revision surgery with removal of the implant.

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.

Reduced 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.

Hayes performed an evidence analysis research brief for Cartiform Viable Osteochondral Allograft (Arthrex) for Treatment of Osteochondral Defects. A review of abstracts suggests that there currently is not enough published peer-reviewed literature to evaluate the evidence related to Cartiform viable osteochondral allograft (OA) (Arthrex) for the treatment of osteochondral defects (Hayes, 2023).

Mehta et al. (2022) assessed short-term clinical outcomes in 18 patients with isolated articular cartilage lesions who were treated with marrow stimulation followed by placement of ProChondrix. There were two reported failures requiring reoperation. Limitations included small sample size and follow-up period. In addition, the procedure was performed by a single surgeon, who also collected, compiled, and analyzed the data. The defects treated in the study were relatively small, focal, contained lesions.

Synthetic Resorbable Polymers

The evidence for use of synthetic resorbable polymers consists mainly of studies performed on animals. Human studies in the published scientific literature are limited and consist mainly of a few case reports and case series. Although some clinical outcomes are encouraging, poor clinical outcomes such as persistent pain, functional deficits and failure of graft incorporation have been reported and lend support to problems with biocompatibility when using synthetic implants for some individuals. Consequently, evidence in the medical literature is insufficient to support the potential value of synthetic resorbable polymers as an alternative to allograft or autograft for the repair of osteochondral defects.

Verhaegen et al. (2015) stated that treatment of osteochondral defects remains a challenge in orthopedic surgery. The TruFit plug has been examined as a potential therapy for osteochondral defects. The TruFit plug is a bi-phasic scaffold designed to stimulate cartilage and subchondral bone formation. Each layer of this synthetic graft is made from a polylactide-co-glycolide copolymer. The authors examined clinical, radiological, and histological effectiveness of the TruFit plug in restoring osteochondral defects in the joint. They performed a systematic search in databases for clinical trials in which patients were treated with a TruFit plug for osteochondral defects. Studies had to report clinical, radiological, or histological outcome data; and quality of the included studies was also assessed. A total of five studies described clinical results, all indicating improvement at follow-up of 12 months compared to pre-operative status. However, two studies reporting longer follow-up showed deterioration of early improvement. Radiological evaluation indicated favorable MRI findings regarding filling of the defect and incorporation with adjacent cartilage at 24 months follow-up, but conflicting evidence existed on the properties of the newly formed overlying cartilage surface. None of the included studies showed evidence for bone ingrowth. The few histological data available confirmed these results. The authors concluded that there

are no data available that support superiority or equality of TruFit compared to conservative treatment or mosaicplasty/micro-fracture (MF). They stated that further investigation is needed to improve synthetic bi-phasic implants as therapy for osteochondral lesions; RCTs comparing TruFit plugs with an established treatment method are needed before further clinical use can be supported.

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/pmnm.cfm>. (Accessed January 23, 2025)

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 January 23, 2025)

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/pmnm.cfm>. (Accessed January 23, 2025)

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/pmnm.cfm>. (Accessed January 23, 2025)

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

2023 Hayes Inc, Evidence Analysis Research Brief. Extracellular Matrix With BioCartilage for Orthopedic Indications. Lansdale, PA: Hayes, Inc., October 2022.

American College of Radiology (ACR). (2025). Key imaging findings for osteoarthritis. Available at: www.acr.org. Accessed on December 3, 2025.

ECRI. BioCartilage Extracellular Matrix (Arthrex, Inc.) for Repairing Cartilage Defects in the Knee. (Product Brief) January 2019.

Farr J, Cole BJ, Sherman S, et al. Particulated articular cartilage: CAIS and DeNovo NT. J Knee Surg. 2012 Mar;25(1):23-9.

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.

Grassi A, Lucidi GA, Filardo G, et al. Minimum 10-Year clinical outcome of lateral collagen meniscal implants for the replacement of partial lateral meniscal defects: further results from a prospective multicenter study. *Orthop J Sports Med.* 2021 May 25;9(5):2325967121994919.

Hayes Inc, Evidence Analysis Research Brief. Cartiform Viable Osteochondral Allograft (Arthrex) for Treatment of Osteochondral Defects. Lansdale, PA: Hayes, Inc., November.

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.

Igarashi T, Kaneko T, Yoshizawa S, et al. Autologous chondrocyte implantation with a Reveille cartilage processor for articular cartilage injury: a case report. *J Surg Case Rep.* 2020 Apr 29;2020.

Johnson CC, Johnson DJ, Garcia GH, et al. High Short-Term Failure Rate Associated With Decellularized Osteochondral Allograft for Treatment of Knee Cartilage Lesions. *Arthroscopy.* Dec 2017; 33(12): 2219-2227.

Kohli S, Schwenck J, Barlow I. Failure rates and clinical outcomes of synthetic meniscal implants following partial meniscectomy: A systematic review. *Knee Surg Relat Res.* 2022.

Lucidi GA, Grassi A, Agostinone P, et al. Risk factors affecting the survival rate of collagen meniscal implant for partial meniscal deficiency: An analysis of 156 consecutive cases at a mean 10 years of follow-up. *Am J Sports Med.* 2022.

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.

Mehta VM, Mehta S, Santoro S, et al. Short term clinical outcomes of a Prochondrix® thin laser-etched osteochondral allograft for the treatment of articular cartilage defects in the knee. *J Orthop Surg (Hong Kong).* 2022; 30(3): 10225536221141781.

Pennsylvania Code and Bulletin, Title 55, Chapter 1101.31. Scope. Refer to: <http://www.pacodeandbulletin.gov/Display/pacode?file=/secure/pacode/data/055/chapter1101/s1101.31.html&d=reduce>. Accessed April 30, 2025.

Quintana JM, Bilbao A, Escobar A, et al. Decision trees for indication of total hip replacement on patients with osteoarthritis. *Rheumatology (Oxford).* 2009 Nov;48(11):1402-9.

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.

Slattery C, Kweon CY. Classifications in brief: Outerbridge classification of chondral lesions. *Clin Orthop Relat Res.* 2018 Oct;476(10):2101-2104.

Verhaegen J, Clockaerts S, Van Osch GJ, et al. TruFit plug for repair of osteochondral defects-where is the evidence? Systematic review of literature. *Cartilage.* 2015;6(1):12-19.

Policy History/Revision Information

Date	Summary of Changes
04/01/2026	<p>Definitions</p> <ul style="list-style-type: none"> • Added definition of: <ul style="list-style-type: none"> ○ Disabling Pain ○ Functional Disability ○ Outerbridge Grades ○ Radiographic Findings of Osteoarthritis ○ Western Ontario and McMaster Universities Arthritis Index (WOMAC) <p>Applicable Codes</p> <ul style="list-style-type: none"> • Updated list of applicable CPT codes to reflect annual edits; removed 27445 <p>Supporting Information</p> <ul style="list-style-type: none"> • Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information • Archived previous policy version CS068PA.Y

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a

conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy 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. The UnitedHealthcare Medical Policies 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.