Surgery of the Knee (for Kansas Only)

Policy Number: CS068KS.05
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➲ Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Kansas.

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, Reveille Cartilage Processor)
- Allogeneic minced or particulated cartilage [e.g., BioCartilage®, DeNovo Natural Tissue (NT) Graft, DeNovo Engineered Tissue (ET) Graft]
- 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: An extracellular matrix consisting of cartilage allograft that is intended to provide a scaffold for microfracture defect. The small particles are mixed with a blood solution to create a paste-like consistency that is applied over a cartilage defect (Hayes, 2022; updated 2025).

Cartilage Autograft Implantation System: 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 and are implantable porous meniscus scaffolds composed of collagen fibers, enriched with glycosaminoglycan; they are used as a template and support for generation of new tissue to replace the lost menisci (Witstein, 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 (Witstein, 2023).

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

DeNovo Natural Tissue (NT) 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 of > 40 (Quintana et al., 2009).

Functional Disability: WOMAC functional limitation domain of > 40 (Quintana et al., 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 of more than 1.5 cm
- Grade IV: Exposed subchondral bone head

(Slattery and Kweon, 2018)

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 (American College of Radiology, 2025).

Reduced Allograft Discs [e.g., Cartiform (Arthrex), ProChondrix CR (Allosource)]: Wafer-thin allografts in which 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 (Mehta et al., 2022).

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

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 (Witstein, 2023).

Western Ontario and McMaster Universities Arthritis Index: The WOMAC is a disease-specific, self-administered questionnaire developed to evaluate individuals with hip or knee osteoarthritis. It uses a multidimensional scale composed of 24 items that are grouped into three dimensions: pain, stiffness, and physical function (Quintana et al., 2009).

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

CPT Code	Description
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. Autologous or allogeneic Minced Cartilage, Decellularized Osteochondral Allograft Plugs, Synthetic Resorbable Polymers, collagen implants, and reduced osteochondral allograft discs are being evaluated as treatments for articular cartilage lesions.

Clinical Evidence

Autologous or Allogeneic Minced or Particulated Cartilage

Minced cartilage techniques are currently undergoing clinical evaluation, and while early results are available, long-term outcomes are still being studied (e.g., particulated juvenile articular cartilage). Early results from case series appear to show similar outcomes to those of other treatments for cartilage defects, but these case series do not allow conclusions regarding the effect of this treatment on long-term 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 are needed, preferably larger randomized controlled trials that directly compare particulated juvenile articular cartilage with other established treatments and that evaluate the effect on health outcomes compared with that of the available procedures.

Hayes conducted an Evolving Evidence Review evaluating a hybrid approach combining autologous chondrocyte implantation with the osteochondral autograft transfer system for the treatment of osteochondral knee defects in adults. Review of the full evidence indicates limited or unclear support for the use of the hybrid autologous chondrocyte implantation with the osteochondral autograft transfer system procedure, including approaches using BioCartilage (Hayes, 2022; updated 2025).

Hayes reviewed the literature for the DeNovo Natural Tissue (NT) Graft for articular cartilage repair of the knee or ankle in an Evolving Evidence Review. The authors concluded that there is no support for the use of this product for the treatment of articular cartilage lesions or defects of the knee. The assessment demonstrated a lack of direct comparative evidence for DeNovo Natural Tissue (NT) Graft use for knee cartilage lesions (Hayes, 2025).

Schneider et al. (2024) conducted a prospective single-arm study in 62 consecutive participants treated with arthroscopic autologous minced cartilage implantation for symptomatic knee cartilage defects and observed clinical improvement at 2 years. The authors' a priori objective was to assess both clinical and radiological outcomes over a 24-month follow-up period. Participant-reported outcomes demonstrated measurable gains, including an increase in the Knee Injury and Osteoarthritis Outcome Score (KOOS) from 62.4 prior to surgery to 74.4 after surgery, with a p value of < 0.001. Improvements were noted on the visual analog scale (VAS) for pain, Western Ontario and McMaster Universities Osteoarthritis Index, and Single Assessment Numeric Evaluation. At 24 months, magnetic resonance imaging (MRI) suggested moderate cartilage repair quality, reflected by a mean Magnetic Resonance Observation of Cartilage Repair Tissue 2.0 score of approximately 63. The overall revision rate was 8.1%, largely attributable to graft hypertrophy, which accounted for 6.5% of cases. The authors concluded that based on the study results, minced cartilage implantation led to good results at 2 years, with participants reporting steady improvement between 3 and 24 months after surgery. MRI scans showed that the repaired cartilage was similar in quality to other treatment methods. However, the radiological findings were limited by the fact that only 20 of the 62 underwent MRI at follow-up, raising concerns about sampling bias because these imaging results may not fully represent the entire cohort. Additionally, the study does not provide evidence on long-term durability. Determining the sustained effectiveness of this technique will require controlled studies that have longer follow-up periods. Important limitations include the lack of a control group, potential sampling bias related to the small subset undergoing MRI, small sample size, susceptibility of the study design to confounding and participant-reported outcome bias, and restricted generalizability due to the single-center setting and relatively short 2-year follow-up period.

In an Evidence Analysis 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 a high risk of bias because of the lack of a control group and randomization, and 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 the use of BioCartilage, and determine whether its use improves clinical outcomes.

Collagen Meniscus Implant

There is insufficient evidence to demonstrate the efficacy of collagen meniscus implants (CMIs) 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.

Lucidi et al. (2024) conducted a prospective case-control study aimed to evaluate the long-term outcomes of medial CMI implantation compared with those of partial medial meniscectomy in participants with medial meniscus injuries. Overall, 36 participants treated between 1997 and 2000 were followed up prospectively, with assessments at 10 years and a final follow-up at 20 years. The authors' a priori objective was to determine whether medial CMI provided superior long-term clinical or radiological outcomes or any evidence of chondroprotection compared with standard meniscectomy. The outcome measures included clinical scores such as Lysholm, International Knee Documentation Committee, KOOS, Tegner activity level, pain VAS, and radiographic evaluations of hip-knee angle and joint line height, along with data on complications and failures. At the 20-year follow-up, 31 participants (mean age, 60.7 years) were analyzed, and similar clinical and radiological results were observed between the two groups. Both groups had low failure rates, with one failure and four reoperations per group. Radiographic findings revealed no significant differences in alignment, joint line height, or osteoarthritis progression. Only 20 of the 31 participants underwent radiological evaluation. The authors concluded that while medial CMI provided good long-term outcomes and low failure rates, it did not demonstrate superior clinical or radiological benefits compared with partial medial meniscectomy, suggesting that the use of a medial scaffold is not chondroprotective in the long term. Medial CMI showed superior clinical and radiographic outcomes vs meniscectomy at 10 years, but this chondroprotective advantage was lost by 20 years. Although meniscal scaffold technology has been in use for over 2 decades, its application remains limited, and there is still a lack of long-term comparative studies in literature. It remains unclear whether scaffolds offer advantages over meniscectomy in terms of functional outcomes or chondroprotection. Study limitations include a small sample size, nonrandomized design, and lack of blinding, which increase susceptibility to selection bias, unmeasured confounding, and assessment bias.

Kohli et al. (2022) performed a systematic review comparing the clinical outcomes and failure rates in individuals 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 individuals following meniscal resection. This was largely due to the high proportion of concurrent procedures carried out at the index procedure for CMI. These investigators stated that based on 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 chondroprotective effects and 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 the clinical outcomes impossible. Third, the inclusion criteria for the individual studies that were 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 randomized controlled trials are needed before meniscal scaffolds can be recommended for routine clinical use. A key limitation of this study is its reliance on predominantly low-level evidence with heterogeneous designs and a high rate of concurrent procedures, making it difficult to isolate the true effectiveness of synthetic meniscal implants.

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 of 10.9 years of follow-up. The authors noted that this study has several limitations, including its retrospective design and lack of a control group. Additionally, 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 chondroprotection or symptom relief compared with isolated meniscectomy. It was not possible to analyze whether the location of the meniscal lesion, degree of meniscectomy, and size of the CMI were risk factors for failure. Finally, there was a considerable percentage of patients who underwent an associated surgical procedure during the CMI surgery. The study's limitations include its single-institution case-control design and absence of a control group, which may restrict generalizability and introduce potential selection and information biases.

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 participants who underwent lateral CMI implantation for partial lateral meniscal defects and who were part of a previous study that had a 2-year follow-up. The outcome measures at the latest follow-up included the Lysholm score, KOOS, 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 participants had good or excellent Lysholm scores. However, there was a general decrease in outcome scores between the short- and long-term follow-ups. 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. These include a limited number of participants, which did not allow the performance of sophisticated statistical subanalyses 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, the cartilage status, and the time of the index surgery could be relevant and should be investigated in studies with a larger sample size. The study is limited by its small sample size, case-series design, and loss to follow-up, which reduce generalizability and increase the risk of bias.

Decellularized Osteochondral Allografts

Existing evidence on decellularized osteochondral allograft plugs has reported delamination of the implants and high failure rates. Further studies, with a larger number of individuals and longer follow-up, are needed, particularly 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 allograft plugs in the treatment of distal femoral osteochondral lesions; 34 individuals were included. Outcomes reported by the individuals, 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 months), 10 individuals (29%) required revision surgery with removal of the implant. The study is limited by its short follow-up duration and high early failure rate, which restrict generalizability and prevent long-term outcome assessment.

Farr et al. (2016) reviewed the records of an institutional review board–approved database and identified a series of 23 participants with prospectively collected data who had been treated with the implant. Participant-reported outcomes, MRI, and the number and type of reoperations were assessed. Failure was defined as structural damage of the graft, which was diagnosed by arthroscopy or MRI, and any reoperation that resulted in removal of the allograft. Participants were evaluated prior to and post operation using the KOOS and Marx Sports Activity Scale. MRI was assessed prior to and post operation. The implant demonstrated a 72% failure rate in the first 2 years of implantation. The study is limited by its short follow-up duration and very high early failure rate, which markedly reduce the generalizability and long-term applicability of its findings.

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 individuals 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 on the Cartiform viable osteochondral allograft (Arthrex) for the treatment of osteochondral defects. A review of abstracts suggests that there currently are not enough published, peer-reviewed literature to evaluate the evidence related to Cartiform viable osteochondral allograft for the treatment of osteochondral defects (Hayes, 2023).

Mehta et al. (2022) assessed the short-term clinical outcomes in 18 individuals with isolated articular cartilage lesions who were treated with marrow stimulation, followed by placement of ProChondrix. There were two reported failures that required reoperation. Limitations include the 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. A major limitation of this study is its small sample size and short follow-up duration, which restrict the generalizability of the findings and prevent assessment of long-term graft durability.

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 in 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 the 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 biphasic scaffold designed to stimulate cartilage and subchondral bone formation. Each layer of this synthetic graft is made from a poly-lactide-co-glycolide copolymer. The authors examined the 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 individuals were treated with a TruFit plug for osteochondral defects. Studies had to report clinical, radiological, or histological outcome data, and the quality of the included studies was also assessed. A total of five studies described clinical results, all indicating improvement at a follow-up of 12 months compared with preoperative status. However, two studies that reported 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 of follow-up, but conflicting evidence exists regarding 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 the superiority or equality of TruFit compared with conservative treatment or mosaicplasty/microfracture. They stated that further investigation is needed to improve synthetic biphasic implants as therapy for osteochondral lesions; randomized controlled trials that compare TruFit plugs with an established treatment method are needed before further clinical use can be supported. Limitations of this study include the low quality; additionally, the small number of available clinical trials and absence of comparative data against established treatments prevent firm conclusions regarding the TruFit plug's effectiveness.

Xenografts

Xenografts for cartilage repair are being investigated as a potential alternative to autografts and allografts, with decellularization intended to reduce immunogenicity and graft rejection; however, the safety and efficacy of this approach remain unproven and require additional high-quality studies.

Bracey et al. (2020) conducted the first systematic review of orthopedic clinical studies on bone xenotransplantation and reported outcomes from a single-center case series. The authors reviewed 31 clinical studies, most commonly in spine surgery, and found mixed results overall: 44% reported favorable outcomes, while 47% reported poor outcomes and discouraged use of xenograft bone. In their own case series of bovine bone xenografts used in foot and ankle reconstruction, xenografts failed to integrate with host bone in 58% of cases, and persistent pain occurred in 83% of individuals. The authors concluded that existing clinical evidence does not support the use of bone xenografts in orthopedic surgery. The study is limited by the heterogeneity and lack of robust comparative trials to support meaningful conclusions about xenograft effectiveness.

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 January 26, 2026)

Transplant 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 (1) FDA registration and requirements for good tissue practices and infectious disease screening and testing and (2) 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 26, 2026)

Collagen meniscus implants, also known as collagen scaffold, are bioresorbable, primarily being 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 January 26, 2026)

Refer to the following website for more information regarding products used for autologous chondrocyte transplant, and search by product name in the device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 26, 2026)

Donor tissue products derived from human cartilage, such as the DeNovo Natural Tissue (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 of the FDA. The Center for Biologics Evaluation and Research (CBER) does not regulate the transplant 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, prepare and follow written procedures for the prevention of the spread of communicable disease, and maintain records.

References

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Policy History/Revision Information

Date	Summary of Changes
06/01/2026	**Definitions** • Updated definition of “BioCartilage” **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS068KS.04

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