MEDICAL POLICY

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Medical Policy Title	**Osteochondral Grafting of the Knee**
Policy Number	**7.01.59**
Current Effective Date	October 15, 2025
Next Review Date	June 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Osteochondral allograft/autograft transplantation (OATS)/mosaicplasty is considered **medically appropriate**, when **ALL** of the following criteria are met:

A. Body Mass Index (BMI) of less than 35;

B. Individual is age 49 years or younger;

C. Absence of inflammatory arthritis or other systemic disease affecting the joints;

D. Presence of **ALL** of the following imaging or arthroscopic findings:

1. Kellgren-Lawrence Grade II or less on radiograph; and
2. Normal articular cartilage at the lesion border (contained lesion);

E. A full-thickness distal femoral articular surface (i.e., medial condyle, lateral condyle, or trochlea) or patellar chondral defect that has been identified with **ANY** of the following:

1. CT arthrogram;
2. MRI and the Modified Outerbridge Classification is Grade III or IV; or
3. Arthroscopy and the Outerbridge Classification is Grade III or IV;

F. Additional imaging findings required based on procedure type:

1. Osteochondral autograft transplants and mosaicplasty also require a small (i.e., ≤ 2.5 cm^2 total) chondral defects with sharp, definite borders surrounded by normal-appearing hyaline cartilage; or
2. Osteochondral allograft transplants also require a large (i.e., ≤10.0 cm^2 total) chondral defects with sharp definite borders surrounded by normal appearing hyaline cartilage;

G. Absence of a Modified Outerbridge Classification Grade III or IV corresponding 'kissing lesion' defect of the distal femur (trochlea, condyles), patella, or tibia is required when performed for femoral and patellar chondral lesions;

H. Physical exam demonstrates **BOTH** of the following findings:

1. A stable knee with intact or reconstructed ligaments (ACL or PCL) and menisci; *Note: A concurrent ligament stabilization or meniscal procedure at the time of OATS would be acceptable; **and**

2. Normal tibial-femoral and/or patella-femoral alignment;

I. Symptoms include function-limiting knee pain or loss of knee function which interferes with the ability to carry out age-appropriate activities of daily living;

J. Failure of provider-directed non-surgical management for at least three (3) months duration.

II. Osteochondral grafting/autograft transplantation (OATS)/mosaicplasty of the distal femoral articular or patellar surface is considered **investigational** for any other indication or condition.

III. Hybrid autologous chondrocyte implantation ~~is~~ performed with osteochondral autograft transfer system (Hybrid Autologous Chondrocyte Implantation/ Osteochondral Autograft Transfer System [ACI/OATS]) technique for the treatment of an osteochondral defect is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

7.01.38 Autologous Chondrocyte Implantation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Osteochondral autografting and allografting have been investigated for full-thickness cartilage defects of weight-bearing surfaces due either to trauma or conditions such as osteochondritis dissecans. Overall, the goal of osteochondral grafting procedures is to re-establish the cartilage matrix with chondrocytes and supporting bone, to improve joint function and decrease pain. The procedure entails the harvesting of one or more small grafts of bone and cartilage from either the patient's non-weight-bearing or less-weight-bearing surfaces (autograft) or from a cadaver joint (fresh or cryopreserved allograft). The base of the defect is then abraded or curetted down to subchondral bone, and the grafts are implanted in the defect. Use of autografting is associated with repairing smaller defects, whereas allografts are utilized for larger defects. The advantages of using autograft material include graft availability, the absence of possible disease transmission risk, and the ability to perform the procedure in a single stage. Disadvantages include donor site morbidity and limit available graft volume. In addition, tissue may have to be harvested from two different donor sites, to provide enough material for a large defect without compromising the donor site. The use of allograft cartilage has the advantages of providing osteochondral segments that are able to survive transplant, the ability to heal to recipient-site tissue, and no associated donor site morbidity. Application of osteochondral allografting is limited, because cryopreserved allografts do not contain an acceptable level of cartilage viability, and cryopreservation may decrease the viability of the cartilage cells. Fresh, osteochondral allografts must be implanted within 72 hours of donor death, may be difficult to obtain (due to scarcity), and may transmit disease. A well-organized transplant

program is required, and the surgery cannot be done on an elective basis.

Several systems are available for performing this procedure: the Mosaicplasty System (Smith and Nephew), the OATS, (Arthrex, Inc.), and the COR and COR2 systems. The OATS procedure involves use of larger plugs, usually filling the entire defect with a single plug, while mosaicplasty uses multiple, small, cylindrical plugs. It is suggested that mosaicplasty reduces the possibility of donor site morbidity and produces a more congruent surface. In both of these techniques, harvesting and transplantation is performed during the same surgical procedure. The COR and COR2 systems can be utilized for autograft or allograft transplantation.

Filling defects with minced articular cartilage (autologous or allogeneic) is another single-stage procedure that is being investigated for cartilage repair. The Cartilage Autograft Implantation System (CAIS; Johnson and Johnson; phase 3 trial) harvests cartilage and disperses chondrocytes on a scaffold in a single-stage treatment. BioCartilage (Arthrex) consists of a micronized allogeneic cartilage matrix that is intended to provide a scaffold for microfracture. DeNovo NT Graft (Natural Tissue Graft) is produced by ISTO Technologies, with exclusive distribution rights by Zimmer. DeNovo NT consists of manually minced cartilage tissue pieces obtained from juvenile allograft donor joints. The tissue fragments are mixed intra-operatively with fibrin glue before implantation in the prepared lesion. It is thought that mincing the tissue helps both with cell migration from the extracellular matrix and with fixation.

Manipulated (decellularized) human tissue graft products (e.g., Chondrofix osteochondral allograft) are made of bone and cartilage tissue that has been harvested from a cadaveric donor and processed, to remove blood, cells, and fat from the tissue. It is sterilized to kill bacteria and other microorganisms, and purportedly promotes bone integration and remodeling, while reducing the risk of inflammation, in repair of Grade III and Grade IV osteochondral lesions. While this product does not require U.S. Food and Drug Administration (FDA) approval, it does require handling and processing from an FDA-accredited tissue bank (LifeNet Health). It also comes in a variety of sizes to treat different defect sizes.

Synthetic grafts are being investigated as alternatives to allografts and autografts. It has been proposed that synthetic grafts could provide a substrate, encouraging bony in-growth and surface repair. Synthetic resorbable polymers (e.g., PolyGraft, TruGraft, and TruFit plugs) are polymer scaffolds that are being proposed for the repair of osteochondral articular cartilage defects. The implant functions as a scaffold for chondral and osteogenic cells, with the synthetic polymer being resorbed as the cells produce their normal matrices. TruFit plugs are synthetic polymer scaffolds that are inserted into an articular surface, to provide a stable scaffold to encourage the regeneration of a full thickness of articular cartilage to repair chondral defects. The clinical value of TruFit plugs for osteochondral allografts of the knee has not been established. The bone graft substitute implant can be used to backfill harvest sites. At this time, the literature is insufficient to support their use.

ProChondrix (AlloSource) and Cartiform (Arthrex) are wafer-thin allografts in which the bony portion of the allograft has been reduced. The discs are laser-etched or porated and contain hyaline cartilage with chondrocytes, growth factors, and extracellular matrix proteins. ProChondrix is available in dimensions from 7 to 20 mm and is stored fresh for a maximum of 28 days. Cartiform is cut to the desired size and shape and is stored frozen for a maximum of two years. The osteochondral discs are

typically inserted after microfracture and secured in place with fibrin glue and/or sutures.

Hybrid Autologous Chondrocyte Implantation (ACI) is combined with other surgical repair techniques of cartilage defects (e.g., osteochondral autograft transfer).

The Kellgren-Lawrence Grading System is a radiographic grading system that has been developed for describing osteoarthritic changes to the knee. When used, the radiographic findings are typically reported within one of the following categories:

- Grade 0 – No radiographic features of osteoarthritis are present;
- Grade I – Doubtful narrowing of joint space and possible osteophytic lipping;
- Grade II – Definite osteophytes and possible narrowing of joint space;
- Grade III – Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis, and possible deformity of bone contour;
- Grade IV – Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour.

Kissing lesion is an articular cartilage defect on opposing joint surfaces of the knee that are in contact between either the patella and distal femur or the distal femur and tibia (e.g., bipolar lesion).

Modified Outerbridge Classification is a system that has been developed for judging articular cartilage injury to the knee. This system allows delineation of varying areas of chondral pathology, based on the qualitative appearance of the cartilage surface as viewed on MRI, and can assist in identifying those injuries that are suitable for repair techniques. The characterization of cartilage in this system is as follows:

- Grade I – softening with swelling;
- Grade II – fragmentation and fissuring less than one square centimeter (1 cm^2);
- Grade III – fragmentation and fissuring greater than one square centimeter (1 cm^2);
- Grade IV – subchondral bone exposed.

Mosaicplasty (or osteochondral cylinder transplantation) is a surgical technique that consists of harvesting cylindrical bone-cartilage grafts and transplanting them into focal chondral or osteochondral defects in the knee. After excision of the chondral lesion, an abrasion arthroplasty is performed to refresh the base of the defect. The grafting procedure involves collecting grafts from the posterior aspect of the distal femoral articular surfaces (medial condyle, lateral condyle, or trochlea) and implanting the grafts in a mosaic-like pattern that will contribute to regeneration and repair the articular surface. A recipient tunnel is created and sized with a drill bit slightly larger than the length of the graft. The harvested graft is placed in the tunnel by a press-fit method. All subsequent grafts are inserted in a similar pattern.

Non-Surgical Management (with regard to the treatment of knee lower extremity joint pain) is any provider-directed non-surgical treatment that has been demonstrated in the scientific literature as efficacious and/or is considered reasonable care in the treatment of lower extremity joint knee pain. The types of treatment involved can include, but are not limited to, the following: ice; relative

rest/activity modification; acupuncture; weight loss; supervised physiotherapy modalities and therapeutic exercises; prescription and non-prescription medications; assistive devices; and/or intra-articular injections.

Osteochondral Allograft Transplantation (OATS) is a procedure that is similar to mosaicplasty, involving the use of a larger, single plug that usually fills an entire defect. It is often performed to graft chondral defects that are also associated with anterior cruciate ligament (ACL) tears. This method allows arthroscopic access to both the ACL and the chondral defect for the performance of a repair and the grafting procedure.

The Outerbridge Classification is a system that has been developed for judging articular cartilage injury to the knee. This system allows delineation of varying areas of chondral pathology, based on the qualitative appearance of the cartilage surface as viewed by direct visualization intraoperatively, and can assist in identifying those injuries that are suitable for repair techniques. The characterization of cartilage in this system is as follows:

- Grade I – softening with swelling;
- Grade II – fragmentation and fissuring less than one square centimeter (1 cm2);
- Grade III – fragmentation and fissuring greater than one square centimeter (1 cm2);
- Grade IV – subchondral bone exposed.

SUPPORTIVE LITERATURE

Evidence is sufficient to consider osteochondral allografting medically appropriate as a technique to repair large (e.g., 10 cm^2), full-thickness chondral defects of the knee caused by acute or repetitive trauma.

Several systematic reviews of randomized controlled trials (RCTs) have evaluated autologous osteochondral transplantation for cartilage repair of the knee in the short- and mid-term. When compared with abrasion techniques (e.g., microfracture, drilling), there is evidence that autologous osteochondral transplantation decreases failure rates and improves outcomes in patients with medium-size lesions (e.g., 2-6 cm^2) when measured at longer follow-up. This is believed to be due to the improved durability of the natural hyaline cartilage compared with the fibrocartilage that is obtained with abrasion techniques. Factors shown to affect success in observational studies are male sex, younger age, and lesions smaller than 3 cm^2. Thus, there is a relatively narrow range of lesion size for which autologous osteochondral transplantation is most effective. In addition, the best results have been observed with lesions on the femoral condyles, although treatment of trochlea and patella lesions also improves outcomes. Correction of malalignment is important for the success of the procedure.

Zamborsky and colleagues (2020) completed a systematic review and network meta-analysis that evaluated the most appropriate surgical interventions for patients with knee articular cartilage defects. A total of 21 articles (from 12 RCTs) were analyzed with a total population of 891 patients. Follow-up varied widely among the included studies, ranging from 12 months to 15 years. Of the surgical interventions evaluated, microfracture was associated with significantly higher failure rates

compared to autologous chondrocyte implantation at 10 years of follow-up. No significant differences in failure rates were seen between microfracture and osteochondral autograft transplantation, matrix-induced autologous chondrocyte implantation, or characterized chondrocyte implantation at 2, 5, and 10 years of follow-up. Osteochondral autograft transplantation was associated with significantly more excellent or good results at >3 years of follow-up as compared to microfracture, whereas microfracture was associated with significantly poorer results as compared to autologous chondrocyte implantation and matrix-induced autologous chondrocyte implantation. No significant differences between the interventions were noted regarding reintervention, biopsy types, or adverse events. Based on efficacy and safety, autologous chondrocyte implantation was ranked as the best intervention for failure outcome at 10 years of follow-up, followed by osteochondral autograft transplantation, then microfracture. Microfracture was consistently ranked worse than cartilage repair techniques for other outcomes including quality of tissue repair and return-to-activity rates.

Minced or Particulated Cartilage

Early results from case series appear to show similar outcomes compared with other treatments for cartilage defects, but these case series do not permit conclusions regarding the effect of this treatment on health outcomes (Tompkins 2013, Farr 2014, Dawkins 2021). Further studies with a larger number of patients and longer follow-up are needed, especially randomized, controlled trials that directly compare particulated juvenile articular cartilage with other established treatments.

Decellularized Osteochondral Allografts or Reduced Allograft Discs

For individuals with full-thickness articular cartilage lesions who receive decellularized osteochondral allograft plugs or reduced osteochondral allograft discs, the evidence includes one small case series on decellularized osteochondral allograft plugs. Relevant outcomes of the case series were symptoms, functional outcomes, quality of life, and treatment-related morbidity. The researchers reported delamination of the implants, with a high failure rate. No studies have been identified with reduced osteochondral allograft discs. The evidence is insufficient to determine the effects of the technology on health outcomes.

The first report on the use of decellularized osteochondral allograft plugs (Chondrofix) was published by Farr and colleagues in 2016. Review of records for 32 patients identified a high failure rate. Failure was defined as structural damage of the graft identified by MRI or arthroscopy, or any reoperation resulting in removal of the allograft, and 23 of 32 (72%) knees were considered failures.

Johnson and colleagues (2017) examined records from an institutional registry of 34 patients who, following a discussion of alternative cartilage repair options, chose treatment with a decellularized osteochondral allograft plug. 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, 10 (29%) patients required revision surgery with removal of the implant. Failure rates were higher for females and larger lesions (p=.005).

Synthetic Products

Verhaegen and colleagues (2015) performed a systematic search in five databases for clinical trials in which patients were treated with a TruFit plug for osteochondral defects. To be included, studies had

to report clinical, radiological, or histological outcome data. The included studies were assessed for quality. 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-month 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 in-growth. 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. They stated that further investigation is needed, to improve synthetic biphasic implants as therapy for osteochondral lesions; randomized, controlled trials comparing TruFit plugs with an established treatment method are needed, before further clinical use can be supported.

PROFESSIONAL GUIDELINE(S)

In 2018, the National Institute for Health and Care Excellence (NICE) issued new guidance on mosaicplasty for symptomatic articular cartilage defects of the knee (IPG607). The guidance states that the evidence for the safety and efficacy of mosaicplasty for knee cartilage defects is adequate to support the use of the procedure.

In 2022, the American Society of Pain and Neuroscience (ASPN) published the Consensus Guidelines on Interventional Therapies for Knee Pain (STEP Guidelines) (Hunter 2022). These guidelines were developed by a multidisciplinary panel of experts, including specialists in pain management, anesthesiology, orthopedic surgery, and rehabilitation medicine. The guideline makes the following recommendation statements:

- "Mosaicplasty is an effective long-term treatment option for patients 18–50 years old with hyaline cartilage lesions 2–5 cm^2 (Level I, Grade A, Consensus Moderate)."
- OAT is an effective for knee joint preservation technique (Level II, Grade C, Consensus Weak).
- For larger lesions, autograft osteochondral harvesting carries to great of risk of morbidity and as such osteochondral allograft transplantation (OAT) has traditionally been used. Laboratory studies demonstrate superior chondrocyte viability with fresh allografts; however, good results and chondrocyte viability have still been demonstrated with frozen grafts implanted within 28 days from harvest."

In 2023, the American Academy of Orthopedic Surgeons' (AAOS) issued an updated clinical practice guideline for the diagnosis and treatment of osteochondritis dissecans (OCD) of the knee. The AAOS was unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature or skeletally mature patients with unsalvageable fragment. This recommendation was made based on a systematic review for the following cartilage repair techniques: abrasion arthroplasty, autologous chondrocyte implantation (ACI), osteochondral allograft and autograft, chondroplasty, microfracture, moscicplasty and osteochondral autograft transplantation (OAT).

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates human cells and tissues intended for human use through the Center for Biologics Evaluation and Research (CBER). Osteochondral grafts are included in these regulations, under Code of Federal Regulation, Title 21, parts 1270 and 1271.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft)
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)

HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
M12.561-M12.569	Traumatic arthropathy, knee (code range)
M17.0-M17.9	Osteoarthritis of knee (code range)
M22.40-M22.42	Chondromalacia patella, knee (code range)
M23.8x1-M23.92	Other and unspecified internal derangement of knee (code range)

Code	Description
M25.861-M25.869	Other specified joint disorders, knee (code range)
M93.261-M93.269	Osteochondritis dessicans knee (code range)
M94.261-M94.269	Chondromalacia of knee (code range)

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based upon our review, osteochondral grafting is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

07/15/04, 08/18/05, 07/20/06, 06/21/07, 05/14/08, 04/16/09, 03/18/10, 03/17/11, 02/16/12, 02/21/13, 02/20/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18, 06/21/18, 06/20/19, 12/19/19, 12/17/20, 06/17/21, 05/19/22, 05/18/23, 10/17/24, 06/26/25

Date	Summary of Changes
06/26/25	• Annual review, policy intent unchanged. Revised conservative treatment criteria.
01/01/25	• Summary of changes tracking implemented.
12/19/02	• Original effective date