

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	OSTEOCHONDRAL GRAFTING OF THE KNEE
Policy Number	7.01.59
Category	Technology Assessment
Effective Date	12/19/02
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Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare 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.

POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer reviewed medical literature, osteochondral autografting and allografting using one or more cores of osteochondral tissue, are considered **medically appropriate** for treatment of cartilaginous defects caused by acute or repetitive trauma in the knee when **ALL** of the following criteria are met:
- Function-limiting pain and a loss of knee function which interferes with the ability to carry out age-appropriate activities of daily living and/or demands of employment;
 - Large, full-thickness chondral defect of the distal femoral articular surface (i.e., medial condyle, lateral condyle or trochlea) and/or patellar chondral defect which has been identified during arthroscopy or during an MRI or CT arthrogram and classified by Modified Outerbridge Scale as Grade III or Grade IV;
 - One of the following applies:
 - Osteochondral *autograft* transplants and mosaicplasty are considered medically appropriate in an individual with small (i.e., less than or equal to 2.5 cm² total) chondral defects with sharp, definite borders surrounded by normal-appearing hyaline cartilage; or
 - Osteochondral *allograft* transplants are considered medically appropriate in an individual with larger (e.g., less than or equal to 10.0 cm² total) chondral defects with sharp, definite borders surrounded by normal-appearing hyaline cartilage;
 - Previous arthroscopic or other traditional surgical procedure (i.e., microfracture, drilling, abrasion, osteochondral graft) which has resulted in an inadequate response;
 - Failure of provider-directed, non-surgical management for at least three (3) months in duration;
 - Presence of BOTH of the following on physical examination:
 - A stable knee with intact or reconstructed ligaments (ACL or PCL);
 - Normal joint alignment.
 - Minimal to absent osteoarthritic changes in the surrounding articular cartilage (i.e., Kellgren-Lawrence Grade 2 or less);
 - Absence of inflammatory arthritis or other systemic disease affecting the joints with normal articular cartilage at the lesion border (contained lesion);
 - Absence of corresponding “kissing lesion” with a Modified Outerbridge Scale of Grade III or Grade IV of the distal femur (trochlea, condyles), tibia or patella;
 - Individual is not a candidate for total knee arthroplasty;
 - Body Mass Index of less than 35; and
 - Age 49 years or younger.
- II. Based upon our criteria and assessment of the peer-reviewed literature, osteochondral grafting of the distal femoral articular or patellar surface has not been medically proven to be effective and, therefore, is considered **investigational** for any other indication or condition including when autologous chondrocyte implantation is

Medical Policy: OSTEOCHONDRAL GRAFTING OF THE KNEE

Policy Number: 7.01.59

Page: 2 of 8

performed in combination with osteochondral autograft transfer system (Hybrid ACI/OATS) for the treatment of osteochondral defects.

Refer to Corporate Medical Policy #7.01.38 regarding Autologous Chondrocyte Implantation.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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, in order 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 limited 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 Osteochondral Autograft Transfer System (OATS, Arthrex, Inc.), and the COR and COR2 systems (DePuy-Mitek). 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 intraoperatively 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 is harvested from a cadaveric donor that has been 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 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.

Medical Policy: OSTEOCHONDRAL GRAFTING OF THE KNEE

Policy Number: 7.01.59

Page: 3 of 8

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 where the bony portion of the allograft is 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 2 years. The osteochondral discs are typically inserted after microfracture and secured in place with fibrin glue and/or sutures.

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 and can assist in identifying those injuries that are suitable for repair techniques. The characterization of cartilage in this system is as follows:

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

RATIONALE

Evidence is sufficient to consider osteochondral allografting medically necessary as a technique to repair large (e.g., 10 cm²), full-thickness chondral defects of the knee caused by acute or repetitive trauma. Use of allografts for large defects of the talus has been reported in small case series. For osteochondral autografting, only 3 relatively small, randomized controlled trials from investigators in Europe have demonstrated improved clinical outcomes with osteochondral autografting of the knee when compared with microfracture. However, controlled studies demonstrate similar benefit to other cartilage resurfacing procedures in appropriately selected patients, and a number of uncontrolled studies indicate that osteochondral autografts can improve symptoms in some patients with focal lesions of articular cartilage of the knee who have failed prior surgical treatment. These patients have limited options.

Overall, there is evidence that osteochondral grafting procedures in defects of the knee demonstrate relief of symptoms and improved function in a subset of patients who had failed conservative management and arthroscopic or other surgical treatments. For knee defects, patients should be skeletally mature with documented closure of growth plates (approximately 15 years of age or older), yet should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (55 years of age or younger). Patient samples/inclusion criteria in currently published studies support this age range.

Minced cartilage techniques are either not approved in the United States and/or in the early stages of development and testing (eg, 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 permit 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 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 1 small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single case series on decellularized osteochondral allograft plugs reported delamination of the implants with a high failure rate. No studies have been

Medical Policy: OSTEOCHONDRAL GRAFTING OF THE KNEE

Policy Number: 7.01.59

Page: 4 of 8

identified with reduced osteochondral allograft discs. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

Synthetic products

Verhaegen and colleagues (2015) performed a systematic search in 5 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. Quality of the included studies was assessed. A total of 5 studies described clinical results, all indicating improvement at follow-up of 12 months compared to pre-operative status. However, 2 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 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/microfracture. They stated that further investigation is needed to improve synthetic biphasic implants as therapy for osteochondral lesions; randomized controlled trials (RCTs) comparing TruFit plugs with an established treatment method are needed before further clinical use can be supported.

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

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) (eg, mosaicplasty) (includes harvesting of the autograft)
29867	osteochondral allograft (eg, mosaicplasty)

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HCPCS Codes

Code	Description
No codes	

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)

Medical Policy: OSTEOCHONDRAL GRAFTING OF THE KNEE

Policy Number: 7.01.59

Page: 5 of 8

Code	Description
M23.8x1- M23.92	Other and unspecified internal derangement of knee (code range)
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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Medical Policy: OSTEOCHONDRAL GRAFTING OF THE KNEE

Policy Number: 7.01.59

Page: 6 of 8

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Medical Policy: OSTEOCHONDRAL GRAFTING OF THE KNEE

Policy Number: 7.01.59

Page: 7 of 8

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Medical Policy: OSTEOCHONDRAL GRAFTING OF THE KNEE

Policy Number: 7.01.59

Page: 8 of 8

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*Key Article

KEY WORDS

Chondral defects, Chondrofix®, COR, COR2, Mosaicplasty, minced cartilage, OATS, osteochondral autograft, osteochondral allograft, osteochondral autograft transfer procedure.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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