MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Osteochondral Grafting of the Knee**
Policy Number	**7.01.59**
Category	**Technology Assessment**
Original Effective Date	**12/19/02**
Committee Approval Date	**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, 06/17/2, 05/19/22, 05/18/23**
Current Effective Date	**05/18/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *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 or Child Health Plus product), 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 STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed 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:
   A. Patient is experiencing function-limiting pain and a loss of knee function that interferes with the ability to carry out age-appropriate activities of daily living and/or demands of employment.
   B. Patient has a large, full-thickness chondral defect of the distal femoral articular surface (i.e., medial condyle, lateral condyle or trochlea) and/or a patellar chondral defect that has been identified during arthroscopy or during magnetic resonance imaging (MRI) or computed tomography (CT) arthrogram and the Modified Outerbridge Classification or Outerbridge Classification is Grade III or Grade IV.
   C. One of the following applies:
      1. Osteochondral autograft transplants and mosaicplasty: Patient has a small (i.e., less than or equal to 2.5 cm^2 total) chondral defect with sharp, definite borders surrounded by normal-appearing hyaline cartilage; or
      2. Osteochondral allograft transplants: Patient has a larger (i.e., less than or equal to 10.0 cm^2 total) chondral defect with sharp, definite borders surrounded by normal-appearing hyaline cartilage.
   D. Patient has failed provider-directed, non-surgical management of at least three months' duration.
   E. Patient has **BOTH** of the following findings, or will, after surgical correction at the time of the graft:
      1. A stable knee with intact or reconstructed ligaments (acute crucial ligament (ACL), posterior cruciate ligament (PCL) and menisci; and
      2. Normal joint alignment.
   F. Patient has minimal-to-absent osteoarthritic changes in the surrounding articular cartilage (i.e., Kellgren-Lawrence Grade II or less);.

G. Patient does not have inflammatory arthritis or other systemic disease affecting the joints, and has normal articular cartilage at the lesion border (contained lesion).
H. Patient does not have corresponding "kissing lesion" with a Modified Outerbridge Classification of Grade III or Grade IV of the distal femur (trochlea, condyles), tibia or patella.
I. Patient is not a candidate for total knee arthroplasty.
J. Patient has a Body Mass Index of less than 35.
K. Patient is 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 performed in combination with osteochondral autograft transfer system (Hybrid Autologous Chondrocyte Implantation/ Osteochondral Autograft Transfer System (ACI/OATS)) for the treatment of osteochondral defects.

Refer to Corporate Medical Policy #7.01.38 Autologous Chondrocyte Implantation.

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

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 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 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 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.

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:

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

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:

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

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:

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

RATIONALE

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. Use of allografts for large defects of the talus has been reported in small case series. For osteochondral autografting, only three 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 demonstrated 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 are 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 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 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 et al. 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.

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.

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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

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
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)
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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*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 upon our review, Osteochondral Grafting is not addressed in National or Regional Medicare coverage determinations or policies.