MEDICAL POLICY

Excellus

SUBJECT: OSTEOCHONDRAL GRAFTING	EFFECTIVE DATE: 12/19/02 REVISED 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
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- ***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 **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. Severe, disabling 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;
   B. Large, full-thickness chondral defect of the distal femoral articular surface (i.e., medial condyle, lateral condyle or trochlea), which has been identified during arthroscopy or during an MRI, classified by Modified Outerbridge Scale as Grade III or Grade IV;
   C. Osteochondral autograft transplants and mosaicplasty are considered medically appropriate in an individual with small (i.e., ≤ 2.5 cm2 total) chondral defects with sharp, definite borders surrounded by normal-appearing hyaline cartilage;
   D. Osteochondral allograft transplants are considered medically appropriate in an individual with larger (e.g., ≤ 10.0 cm2 total) chondral defects with sharp definite borders surrounded by normal appearing hyaline cartilage;
   E. Previous arthroscopic or other traditional surgical procedure (i.e., microfracture, drilling, abrasion, osteochondral graft) which has resulted in an inadequate response;
   F. Failure of non-surgical management for at least three (3) months in duration;
   G. Presence of ALL of the following on physical examination:
      1. A stable knee with intact or reconstructed ligaments (ACL or PCL);
      2. Normal joint alignment; and
      3. Normal joint space;
   H. Absence of osteoarthritis or generalized tibial chondromalacia, steroid-induced cartilage or bone disease, with normal articular cartilage at the lesion border;
   I. Absence of corresponding tibial or patellar lesion ("kissing lesion") with a Modified Outerbridge Scale of Grade III or Grade IV;
   J. Individual is not a candidate for total knee arthroplasty;
   K. Body Mass Index of less than 35;
   L. Age 49 years or younger; and
   M. Individual must be capable and willing to participate in an extensive period of non-weight bearing and supervised post-operative physical rehabilitation program.

II. Based upon our criteria and assessment of the peer-reviewed literature, osteochondral grafting has not been medically proven to be effective and is **investigational** in the following circumstances**:**
   A. For use in joints other than the knee;
   B. When using autologous or allogeneic minced cartilage preparations;
   C. When using synthetic resorbable polymers (e.g., TruFit Plug, PolyGraft);
   D. When using manipulated or decellarized human tissue graft products (e.g., Chondrofix); or
   E. When using reduced osteochondral allograft discs (e.g., Prochondrix, Cartiform).

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

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 auto-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 one or more small grafts of bone and cartilage being harvested from either the patient's non-weight bearing surfaces/surfaces that bear less weight (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 that the procedure is a single-stage procedure. Disadvantages include donor site morbidity and limited available graft volume. In addition, tissue may have to be harvested from two different donor sites in order to provide enough material for a large defect without compromising the donor site. The use of allograft cartilage has the advantage of providing osteochondral segments that are able to survive transplant, having 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 also entail a concern of disease transmission. 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 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.

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 (eg, PolyGraft, TruGraft 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 Plug 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 and talus 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.

Evidence evaluating treatment in other articular cartilage defects (e.g., shoulder, elbow, hip) is insufficient to support clinical utility of osteochondral grafting due to short outcomes and small sample populations. Better designed studies with larger patient populations and longer-term follow-up are necessary to determine the use of osteochondral grafting results in improved clinical outcomes in other defects other than the knee and talus.

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.

Decellarized osteochondral allografts or reduced allograft discs

For individuals who have 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 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 months follow-up, but conflicting evidence existed on the properties of the newly formed overlying cartilage surface. None of the included studies showed evidence for bone ingrowth. The few histological data available confirmed these results. The authors concluded that there are no data available that support superiority or equality of TruFit compared to conservative treatment or mosaicplasty/micro-fracture. 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: Number Description

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:	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)

HCPCS:	No code	
ICD10:	M22.40-M22.42	Chondromalacia patella, knee (code range)
	M23.8x1-M23.92	Other internal derangement of knee (code range)
	M93.261-M93.269	Osteochondritis dessicans knee (code range)
	M93.271-M93.279	Osteochondritis dessicans ankle and joint of foot (code range)

M94.261-M94.269 Chondromalacia of knee (code range)

M94.271-M94.279 Chondromalacia of ankle and joints of foot (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 on our review, osteochondral grafting is not addressed in National or Regional Medicare coverage determinations or policies.