Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

POLICY NUMBER

A.7.01.78

DESCRIPTION

Osteochondral grafts are used to repair of full-thickness chondral defects involving a joint. In the case of osteochondral autografts, one or more small osteochondral plugs are harvested from non-weight-bearing sites, usually from the knee, and press fit into a prepared site in the lesion. Osteochondral allografts are typically used for larger lesions. Autologous or allogeneic minced cartilage, decellularized osteochondral allograft plugs, and reduced osteochondral allograft discs are also being evaluated as a treatment of articular cartilage lesions.

Articular Cartilage Lesions

Damaged articular cartilage can be associated with pain, loss of function, and disability, and can lead to debilitating osteoarthrosis over time. These manifestations can severely impair an individual’s activities of daily living and quality of life. The vast majority of osteochondral lesions occur in the knee with the talar dome and capitulum being the next most frequent sites. The most common locations of lesions are the medial femoral condyle (69%), followed by the weight-bearing portion of the lateral femoral condyle (15%), the patella (5%), and trochlear fossa. Talar lesions are reported to be about 4% of osteochondral lesions.

Treatment

There are two main goals of conventional therapy for patients who have significant focal defects of the articular cartilage: symptom relief and articular surface restoration.

First, there are procedures intended primarily to achieve symptomatic relief: débridement (removal of debris and diseased cartilage), and rehabilitation. Second, there are procedures intended to restore the articular surface. Treatments may be targeted to the focal cartilage lesion and most

such treatments induce local bleeding, fibrin clot formation, and resultant fibrocartilage growth. These marrow stimulation procedures include: abrasion arthroplasty, microfracture, and drilling, all of which are considered standard therapies.

Microfracture

Efficacy of the microfracture technique for articular cartilage lesions of the knee was examined in a 2009 systematic review. Twenty-eight studies (total N=3122 patients) were selected; 6 studies were randomized controlled trials. Microfracture was found to improve knee function in all studies during the first 24 months after the procedure, but the reports on durability were conflicting. A prospective longitudinal study of 110 patients by Solheim and colleagues found that, at a mean of 12 years (range, 10-14 years) after microfracture, 45.5% of patients had poor outcomes, including 43 patients who required additional surgery. The size of the lesion has also been shown to affect outcomes following marrow stimulation procedures.

Abrasion

Fibrocartilage is generally considered to be less durable and mechanically inferior to the original articular cartilage. Thus various strategies for chondral resurfacing with hyaline cartilage have been investigated. Alternatively, treatments of very extensive and severe cartilage defects may resort to complete replacement of the articular surface either by osteochondral allotransplant or artificial knee replacement.

Osteochondral Grafting

Autologous or allogeneic grafts of osteochondral or chondral tissue have been proposed as treatment alternatives for patients who have clinically significant, symptomatic, focal defects of the articular cartilage. It is hypothesized that the implanted graft’s chondrocytes retain features of hyaline cartilage that is similar in composition and property to the original articulating surface of the joint. If true, the restoration of a hyaline cartilage surface might restore the integrity of the joint surface and promote long-term tissue repair, thereby improving function and delaying or preventing further deterioration.

Both fresh and cryopreserved allogeneic osteochondral grafts have been used with some success, although cryopreservation decreases the viability of cartilage cells, and fresh allografts may be difficult to obtain and create concerns regarding infectious diseases. As a result, autologous osteochondral grafts have been investigated as an option to increase the survival rate of the grafted cartilage and to eliminate the risk of disease transmission. Autologous grafts are limited by the small number of donor sites; thus allografts are typically used for larger lesions. In an effort to

extend the amount of the available donor tissue, investigators have used multiple, small osteochondral cores harvested from various non-weight-bearing sites in the knee for treatment of full-thickness chondral defects. Several systems are available for performing this procedure: the Mosaicplasty System (Smith & Nephew), the OATS (Osteochondral Autograft Transfer System; Arthrex), and the COR and COR2 systems (DePuy Mitek). Although mosaicplasty and autologous osteochondral transplantation (AOT) may use different instrumentation, the underlying mode of repair is similar (i.e., the use of multiple osteochondral cores harvested from a non-weight-bearing region of the femoral condyle and autografted into the chondral defect). These terms have been used interchangeably to describe the procedure.

Preparation of the chondral lesion involves debridement and preparation of recipient tunnels. Multiple individual osteochondral cores are harvested from the donor site, typically from a peripheral non-weight-bearing area of the femoral condyle. Donor plugs range from 6 mm to 10 mm in diameter. The grafts are press fit into the lesion in a mosaic-like fashion into the same-sized tunnels. The resultant surface consists of transplanted hyaline articular cartilage and fibrocartilage, which is thought to provide "grouting" between the individual autografts. Mosaicplasty or AOT may be performed with either an open approach or arthroscopically. Osteochondral autografting has also been investigated as a treatment of unstable osteochondritis dissecans lesions using multiple dowel grafts to secure the fragment. While osteochondral autografting is primarily performed on the femoral condyles of the knee, osteochondral grafts have also been used to repair chondral defects of the patella, tibia, and ankle. With osteochondral autografting, the harvesting and transplantation can be performed during the same surgical procedure. Technical limitations of osteochondral autografting are difficulty in restoring concave or convex articular surfaces, incongruity of articular surfaces that can alter joint contact pressures, short-term fixation strength and load-bearing capacity, donor site morbidity, and lack of peripheral integration with peripheral chondrocyte death.

Reddy and colleagues evaluated donor-site morbidity in 11 of 15 patients who had undergone graft harvest from the knee (mean, 2.9 plugs) for treatment of osteochondral lesions of the talus. At an average 47-month follow-up (range, 7-77 months), 5 patients were rated as having an excellent Lysholm Knee Scale score (95-100 points), 2 as good (84-94 points), and 4 as poor (≤64 points). The reported knee problems were instability in daily activities, pain after walking 1 mile or more, slight limp, and difficulty squatting. Hangody and colleagues reported that some patients had slight or moderate complaints with physical activity during the first postoperative year, but there was no long-term donor-site pain in a series of 36 patients evaluated 2 to 7 years after AOT.

Filling defects with minced or particulated articular cartilage (autologous or allogeneic), is another single-stage procedure that is being investigated for cartilage repair. The Cartilage Autograft Implantation System (CAIS, Johnson & Johnson) harvests cartilage and disperses chondrocytes on a

scaffold in a single-stage treatment. The Reveille Cartilage Processor (Exactech Biologics) has a high-speed blade and sieve to cut autologous cartilage into small particles for implantation. 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 and distributed 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.

A minimally processed osteochondral allograft (Chondrofix; Zimmer) is now available. Chondrofix is composed of decellularized hyaline cartilage and cancellous bone; it can be used "off the shelf" with precut cylinders (7-15 mm). Multiple cylinders may be used to fill a larger defect in a manner similar to AOT or mosaicplasty.

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.

Autologous chondrocyte implantation is another method of cartilage repair involving the harvesting of normal chondrocytes from normal non-weight-bearing articular surfaces, which are then cultured and expanded in vitro and implanted back into the chondral defect. Autologous chondrocyte implantation is considered separately in the Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions (https://www.bcbsms.com/medical-policy-search#/policy-detail?id=0ec58001-03c3-479f-b7e8-374e363a48b4) medical policy.

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, title 21, parts 1270 and 1271. Osteochondral grafts are included in these regulations.

DeNovo® ET Live Chondral Engineered Tissue Graft (Neocartilage) is marketed by ISTO Technologies outside of the United States. FDA approved ISTO's investigational new drug application for Neocartilage in 2006, which allowed ISTO to pursue phase 3 clinical trials of the product in human subjects. However, ISTO's clinical trial for Neocartilage was terminated due to poor enrollment as of August 31, 2017.

Also, see the Meniscal Allografts and Other Meniscal Implants (https://www.bcbsms.com/medical-policy-search#/policy-detail?id=871f4280-6ec3-4e74-b578-720b7fd91ceb) medical policy.

POLICY

Osteochondral fresh allografting may be considered **medically necessary** as a technique to repair:

- Full-thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (eg, microfracture, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to lesion size, location, or depth.
- Large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location.
- Revision surgery after failed prior marrow stimulation for large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth or location.

Osteochondral allografting for all other joints is considered **investigational.**

Osteochodral autografting, using one or more cores of osteochondral tissue, may be considered **medically necessary:**

- For the treatment of symptomatic full-thickness cartilage defects of the knee caused by acute or repetitive trauma in patients who have had an inadequate response to a prior surgical procedure, when all of the following have been met:
    - Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years)
    - Focal, full-thickness (grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles, trochlea, or patella that are between 1 and 2.5cm^2 in size
    - Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less), and normal-appearing hyaline cartilage surrounding the border of the defect
    - Normal knee biomechanics, or alignment and stability achieved concurrently with osteochondral grafting.
- Large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the talus.
- Revision surgery after failed marrow stimulation for osteochondral lesion of the talus.

Osteochondral autografting for all other joints and any indications other than those listed above is considered **investigational.**

Treatment of focal articular cartilage lesions with autologous minced or particulated cartilage is considered **investigational.**

Treatment of focal articular cartilage lesions with allogeneic minced or particulated cartilage is considered **investigational.**

Treatment of focal articular cartilage lesions with decellularized osteochondral allograft plugs (eg, Chondrofix) is considered **investigational**.

Treatment of focal articular cartilage lesions with reduced osteochondral allograft discs (eg, ProChondrix, Cartiform) is considered **investigational**.

POLICY EXCEPTIONS

Federal Employee Program (FEP) may dictate that all FDA-approved devices, drugs or biologics may not be considered investigational and thus these devices may be assessed only on the basis of their medical necessity.

POLICY GUIDELINES

The coverage guidelines outlined in the Medical Policy Manual should not be used in lieu of the Member's specific benefit plan language.

If debridement is the only prior surgical treatment, consideration should be given to marrow-stimulating techniques before osteochondral grafting is performed, particularly for lesions less than 1.5 cm^2 in area or 3.0 cm^3 in volume.

Severe obesity (e.g., body mass index greater than 35 kg/m^2) may affect outcomes due to the increased stress on weight-bearing surfaces of the joint.

Misalignment and instability of the joint are contraindications. Therefore additional procedures, such as repair of ligaments or tendons or creation of an osteotomy for realignment of the joint, may be performed at the same time. In addition, meniscal allograft transplantation may be performed in

combination, either concurrently or sequentially, with osteochondral allografting or osteochondral autografting.

Medically Necessary is defined as those services, treatments, procedures, equipment, drugs, devices, items or supplies furnished by a covered Provider that are required to identify or treat a Member's illness, injury or Nervous/Mental Conditions, and which Company determines are covered under this Benefit Plan based on the criteria as follows in A through D:

A. consistent with the symptoms or diagnosis and treatment of the Member's condition, illness, or injury; and

B. appropriate with regard to standards of good medical practice; and

C. not solely for the convenience of the Member, his or her Provider; and

D. the most appropriate supply or level of care which can safely be provided to Member. When applied to the care of an Inpatient, it further means that services for the Member's medical symptoms or conditions require that the services cannot be safely provided to the Member as an Outpatient.

For the definition of Medically Necessary, "standards of good medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, and physician specialty society recommendations, and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors. BCBSMS makes no payment for services, treatments, procedures, equipment, drugs, devices, items or supplies which are not documented to be Medically Necessary. The fact that a Physician or other Provider has prescribed, ordered, recommended, or approved a service or supply does not in itself, make it Medically Necessary.

Investigative is defined as the use of any treatment procedure, facility, equipment, drug, device, or supply not yet recognized as a generally accepted standard of good medical practice for the treatment of the condition being treated and; therefore, is not considered medically necessary. For the definition of Investigative, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, and physician specialty society recommendations, and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors. In order for equipment, devices, drugs or supplies [i.e, technologies], to be considered not investigative, the technology must have final approval from the appropriate governmental bodies, and scientific evidence must permit conclusions concerning the effect of the technology on health

outcomes, and the technology must improve the net health outcome, and the technology must be as beneficial as any established alternative and the improvement must be attainable outside the testing/investigational setting.

POLICY HISTORY

2/2001: Approved by Medical Policy Advisory Committee (MPAC); Mosaicplasty considered investigational.

5/2001: Reviewed by MPAC; Mosaicplasty separated from ACT policy, investigational status maintained.

8/2001: Reviewed by MPAC; investigational status maintained; no policy exceptions.

2/8/2002: Investigational definition added.

2/19/2002: 2002 CPT Category III codes added, CPT 0012T, 0013T added.

5/2/2002: Type of Service and Place of Service deleted.

3/25/2004: Reviewed by MPAC, policy title "Mosaicplasty" renamed "Osteochondral Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions", Mosaicplasty remains investigational, OATS procedure considered investigational, Sources updated.

5/19/2004: Code Reference section reviewed, no changes.

3/23/2005: Code Reference section updated, CPT code 0012T deletion date of 12/31/2004 and Note: "See CPT code 29866" added, CPT code 0013T deletion date of 12/31/2004 and Note: "See CPT code 27415 and 29867" added, CPT code 27415, 29866, 29867 with effective date of 1/1/2005 added, ICD-9 procedure code 81.47 added.

3/9/2006: Coding updated. CPT-4/HCPCS 2006 revisions added to policy.

12/19/2007: Coding updated per 2008 CPT/HCPCS revisions.

12/5/2008: Policy reviewed, policy statement changed and medically necessary indications included in new policy statement.

12/22/2008: Code Reference section updated; CPT codes 27415-27416, 29866-29867 and ICD-9 procedure code 81.47 moved to covered.

06/03/2010: Policy description and guidelines updated regarding treatment approaches. Policy statement unchanged. FEP verbiage added to the Policy Exceptions section. Deleted outdated references from the Sources section. Added CPT code 28446.

08/23/2011: Deleted "Absence of meniscal pathology" from the osteochondral autografting coverage criteria. Separated the investigational policy statement for autograft and allograft.

07/17/2012: Policy reviewed; no changes.

10/25/2013: Added the following investigational policy statements: Treatment of focal articular cartilage lesions with autologous minced cartilage is considered investigational. Treatment of focal articular cartilage lesions with allogeneic minced cartilage is considered investigational.

10/30/2014: Policy title changed from "Osteochondral Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions" to "Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions" to reflect the scope of the policy. Policy description updated regarding available grafts. Osteochondral autografting for patellar lesions changed from investigational to medically necessary. Policy guidelines updated regarding meniscal allograft transplantation.

08/25/2015: Code Reference section updated to add ICD-10 codes. Moved CPT code 28446 to the Investigational Codes table.

01/25/2016: Policy description updated. Policy statement revised to state that osteochondral allografting may be considered medically necessary as a technique to repair full-thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (eg, microfracture, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to the size, location, or depth of the lesion. It previously stated: Osteochondral allografting may be considered medically necessary as a technique to repair large (e.g., 10 cm squared) full thickness chondral defects of the knee caused by acute or repetitive trauma. Policy guidelines updated to add medically necessary and investigative definitions.

05/31/2016: Policy number A.7.01.78 added.

12/13/2017: Policy description updated regarding articular cartilage lesions and treatment. Policy statement updated to state that osteochondral allografting may be considered medically necessary to repair large or cystic osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location; and for revision surgery after failed prior marrow stimulation for large or cystic osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location. Policy statement updated to state that osteochondral autografting may be considered medically necessary for large or cystic osteochondral lesions of the talus and for

revision surgery after failed marrow stimulation for osteochondral lesion of the talus. Removed the talar joint as investigational. Added the following statements: 1) Treatment of focal articular cartilage lesions with decellularized osteochondral allograft plugs is considered investigational. 2) Treatment of focal articular cartilage lesions with reduced osteochondral allograft discs is considered investigational. Policy Guidelines updated. Code Reference section updated to move CPT code 28446 from investigational to covered.

05/04/2018: Policy description updated regarding cartilage repair. Added clinical trial information. Investigational policy statements regarding minced cartilage updated to add "or particulated" cartilage.

SOURCE(S)

Blue Cross Blue Shield Association policy # 7.01.78

CODE REFERENCE

This may not be a comprehensive list of procedure codes applicable to this policy.

The code(s) listed below are ONLY medically necessary if the procedure is performed according to the "Policy" section of this document.

Covered Codes

Code Number	**Description**
CPT-4	
27415	Osteochondral allograft, knee, open
27416	Osteochondal autograft(s), knee, open (eg. mosaicplasty) (includes harvesting of autograft[s])
28446	Open osteochondral autograft, talus (includes obtaining graft[s])

29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) (includes harvesting of the autograft[s])
29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)

HCPCS	

ICD-9 Procedure		**ICD-10 Procedure**	
81.47	Other repair of knee	0SQC0ZZ, 0SQC4ZZ, 0SQD0ZZ, 0SQD4ZZ	Repair of knee, by Approach (Open or Percutaneous Endoscopic)
		0SUC0KZ	Supplement Right Knee Joint with Nonautologous Tissue Substitute, Open Approach
		0SUD0KZ	Supplement Left Knee Joint with Nonautologous Tissue Substitute, Open Approach
		0SUC07Z	Supplement Right Knee Joint with Autologous Tissue Substitute, Open Approach
		0SUD07Z	Supplement Left Knee Joint with Autologous Tissue Substitute, Open Approach
		0SUC47Z	Supplement Right Knee Joint with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
		0SUD47Z	Supplement Left Knee Joint with Autologous Tissue Substitute, Percutaneous Endoscopic Approach

		0SUC4KZ	Supplement Right Knee Joint with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
		0SUD4KZ	Supplement Left Knee Joint with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
ICD-9 Diagnosis		**ICD-10 Diagnosis**	