Independence

Commercial
Medical Policy

Medical Policy Bulletin

Title: **Osteochondral Allograft Transplantation**

Policy #: **11.14.12e**

This policy is applicable to the Company's commercial products only. Policies that are applicable to the Company's Medicare Advantage products are accessible via a separate Medicare Advantage policy database.

The Company makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on contract, and

individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Medical Policy Bulletin document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged or new medical literature may have been published. This Medical Policy Bulletin will be reviewed regularly and be updated as scientific and medical literature becomes available. For more information on how Medical Policy Bulletins are developed, go to the About This Site section of this Medical Policy Web site.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's contract.

MEDICALLY NECESSARY

OSTEOCHONDRAL ALLOGRAFT TRANSPLANTATION FOR ARTICULAR CARTILAGE LESIONS OF THE KNEE
Osteochondral allograft transplantation is considered medically necessary and, therefore, covered for the treatment of full thickness **chondral** defects of the knee caused by acute or repetitive trauma when other treatments (e.g., microfracture, resurfacing) would be inadequate due to size, location or depth of the lesion.

OSTEOCHONDRAL ALLOGRAFT TRANSPLANTATION FOR ARTICULAR CARTILAGE LESIONS OF

THE TALUS

Osteochondral allograft transplantation is considered medically necessary and, therefore, covered for the treatment of **chondral** defects of the talus, when the following criteria for the lesion are met:

- 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.

EXPERIMENTAL/INVESTIGATIONAL

All other uses of osteochondral allograft transplantation are considered experimental/investigational and, therefore, not covered because their safety and/or effectiveness cannot be established by review of the available published literature.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

Guidelines

Osteochondral allograft transplantation has been shown to be most successful in individuals who are 55 years of age or younger.

CHONDRAL INJURY GRADING SYSTEMS

INTERNATIONAL CARTILAGE REPAIR SOCIETY (ICRS)

- Grade 0: Normal
- Grade I: Nearly normal (soft indentation and/or superficial fissures and cracks)
- Grade II: Abnormal (lesions extending down to < 50% of cartilage depth)
- Grade III: Severely abnormal (cartilage defects > 50% of cartilage depth)
- Grade IV: Severely abnormal (through the subchondral bone)

OUTERBRIDGE SYSTEM

- Grade I: Softening and swelling of cartilage
- Grade II: Fragmentation and fissuring, less than 0.5 in. diameter
- Grade III: Fragmentation and fissuring, greater than 0.5 in. diameter
- Grade IV: Erosion of cartilage down to exposed subchondral bone

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, osteochondral allograft transplantation is covered under the medical benefits of the Company's products when the medical necessity criteria listed in this medical policy are met.

Description

Hyaline cartilage found on the articular surface of human joints is flexible and elastic but has little regenerative ability. Traumatic injury to a joint that interferes with smooth joint motion can result in severe pain and instability and often leads to degenerative conditions. Osteochondral defects (OCD) of the knee and ankle often fail to heal on their own and are often associated with pain, disability, loss of function, and

long-term complications of osteoarthritis.

Various methods of cartilage resurfacing have been investigated, including marrow-stimulation techniques such as subchondral drilling, microfracture (MF), and abrasion arthroplasty. These procedures are considered standard therapies and attempt to restore the articular surface by including the growth of fibrocartilage into the **chondral** defect. However, fibrocartilage does not share the same biochemical properties as hyaline cartilage. Compared to the original hyaline cartilage, fibrocartilage has less capability to withstand shock or shearing force. It can also degenerate over time, which results in symptom recurrence. Therefore, various treatment strategies for **chondral** resurfacing with hyaline cartilage have been investigated, including osteochondral autograft transplantation (OAT) and autologous chondrocyte implantation (ACI). These may result in the formation of some hyaline tissue but are only recommended for small defects.

Osteochondral cadaver allografting is an alternative for the repair of large, full-thickness osteochondral knee and ankle defects (e.g., > 1.5 cm^2). Fully formed grafts that match the size and contour of the defect are harvested from the exact donor site of the defect being repaired. During arthrotomy, the defect is fully debrided, and the allograft is implanted and secured with screws. Transplantation of intact articular cartilage avoids the morbidity that may occur from harvesting autografts; in addition, the allograft makes it easier to contour the surface and attain the required height of the damaged cartilage. Donors must be between 15 and 45 years of age, and grafts must be processed within 24 hours of death. Transplantation should be performed within 72 hours of processing, although some investigators have extended the window to five to seven days post-processing. Studies are underway to assess the optimum storage time for fresh allografts.

Potential disease transmission is a disadvantage of fresh allografts. Strict guidelines set up by tissue banks for fresh tissue have reduced, but not completely eliminated, the risk of disease transmission. Although freezing the tissue reduces disease transmission risk, it also destroys viable chondrocytes. Cryopreservation is an alternative to freezing, but studies have shown diminished chondrocyte viability at rates of up to 70 percent. Other disadvantages of osteochondral allograft transplantation include the scarcity of available tissue and problems associated with procurement and handling.

The dense, avascular nature of intact hyaline cartilage tends to afford protection from host response, and removing marrow components can attenuate the response to blood and bone marrow cells in allograft bone. Consequently, at this time, immunology of fresh allogenic transplants is not an issue, and the donor and recipient are not matched for immunologic response.

Most investigators agree that osteochondral allograft transplantation should be offered for full-thickness unipolar osteochondral defects larger than 1.5 cm^2 size resulting from trauma or osteochondritis dissecans in individuals who have failed a prior cartilage resurfacing procedure. In addition, it has been shown that allografting is more likely to succeed when provided to active individuals younger than 55 years of age with stable knees and intact menisci. Investigators have reported the use of osteochondral allograft transplantation for the treatment of osteochondral lesions of the talar dome when osteochondral autograft transplantation may be inadequate due to lesion size, depth, or location (e.g. talar shoulder). The published literature, mainly, small case series and a review of those series indicate good-to-excellent results and suggest osteochondral allograft transplantation should be offered for large (1.5 cm^2) or cystic (>3.0 cm^3) osteochondral lesions of the talas, which due to size, location, or depth of the lesion treatment with osteochondral autograft transplantation would be inadequate.

According to the American Academy of Orthopaedic Surgeons (AAOS), most candidates eligible for articular cartilage restoration are young adults with a single injury or lesion. Older individuals, or those with many lesions in one joint, are less likely to benefit from articular cartilage restoration surgery. If a cartilage defect is too large for an autograft, an osteochondral allograft may be considered.

Contraindications to osteochondral allograft transplantation include inflammatory arthritis, steroid dependency, uncorrected malalignment, ligament insufficiency, or any other conditions that may affect graft incorporation.

Transplantation requires arthrotomy with extensive post-operative rehabilitation. Continuous passive motion is provided post-operatively, and non-weight bearing is recommended for as long as 12 weeks post-surgery; return to normal activities with full weight bearing takes 16 weeks. Participation in sports is not

recommended until six months post-surgery.

Osteochondral allograft transplantation has a 20-year clinical history. Most available studies are retrospective evaluations of outcomes on series of consecutive individuals after variable periods of time. Studies that have been published are compromised by incomplete follow-up for many individuals. However, clinical results of osteochondral allograft transplantation have demonstrated a success rate ranging from 60% to 95%, as defined by graft survival and good/excellent patient evaluations. Long-term follow-up of individuals receiving fresh osteochondral allografts revealed allograft survival rates of 95%, 80%, and 65% at 5, 10, and 15 years, respectively.

PEER-REVIEWED LITERATURE

In a retrospective study, Meyers et al. (1989) evaluated the safety and effectiveness of osteochondral allograft transplantation in the knees of 58 individuals. Preoperative diagnoses included chondromalacia or degenerative arthritis of the patella, osteochondritis dissecans, and unicompartmental traumatic arthritis of the knee. All individuals had disabling knee pain after previous failed attempts to treat their respective diagnoses surgically. Thirty-nine individuals representing 40 knees were available for follow-up at 2 to 10 years post-transplantation. Based on Merle D'Aubigné and Postel score systems, pain, function, and range of motion were rated using a modified clinical hip-rating system with an 18-point scale (higher scores indicating greater function). Eighteen points indicated excellent function, 15 to 17 points indicated good function, 12 to 15 points indicated fair function, and scores less than 12 points indicated poor function. Seventy-eight percent of transplants (n=31) were successful. Thirteen of the successful transplants rated their outcomes as excellent, 14 as good, and 4 as fair. The rate of success for unicompartmental traumatic arthritis was only 30%. The authors concluded that transplantation of a fresh osteochondral allograft was a satisfactory intermediate procedure for the treatment of disabling conditions, with the exception of unicompartmental traumatic arthritis. The study is limited in its small sample size, lack of a comparative group, retrospective nature, and heterogeneous study population.

In a retrospective study, Chu et al. (1999) evaluated the safety and effectiveness of osteochondral allograft transplantation in 55 consecutive individuals representing 55 knees. Eighty-two percent of study

participants were younger than 45 years of age, and the average follow-up was 75 months (11 to 147 months). Patients were evaluated with an 18-point scale, with 6 points allocated to pain, range of motion, and function, respectively. An excellent knee was pain free, had full range of motion, and permitted unlimited activity. A good knee allowed for full-time employment and moderate activity. Seventy-six percent of allografts (11 of 15) transplanted 10 or more years ago were still good or excellent at time of last follow-up. Overall, 76% (36 of 43) received transplants that were rated good or excellent. Eighty-four percent of individuals with unipolar transplants (36 of 43) regained normal use of their resurfaced knee. The results after bipolar resurfacing indicated that only 50% of knees (6 of 12) were rated good or excellent. The authors concluded that fresh osteochondral allograft transplantation was safe and effective for the treatment of large, full-thickness articular cartilage defects to the medial or lateral femoral condyles and to the patella. The study is limited in its small sample size, lack of a comparative group, and retrospective nature.

In a retrospective study, Jamali et al. (2005) evaluated the safety and effectiveness of osteochondral allograft transplantation in 18 individuals representing 20 knees. The mean age of the study participants was 42 years (19 to 64), with fresh osteochondral allografting limited to the patellofemoral joint. Patients were followed for a mean of 94 months (24 to 214). The trochlea and patella were treated in 12 individuals and the patella was treated in 8 individuals. Primary outcome measurements included revision allografting, arthrodesis (artificial induction of joint ossification between two bones to relieve intractable pain), and clinical scoring using a modified Merle D'Aubigné-Postel 18-point scale. Of the 15 knees with successful outcomes, the clinical scores increased from a mean of 11.7 points (7 to 15) to 16.3 points (12 to 18). Of the 12 knees evaluated radiographically, 4 had no evidence of patellofemoral arthrosis, and 6 only had mild arthrosis. The authors concluded that fresh osteochondral allografting is an appropriate salvage procedure for young, active individuals with severe articular cartilage disease of the patellofemoral joint. The study is limited in its small sample size, retrospective study design, relatively short-term follow-up period, and a lack of a comparative group. Moreover, the modified Merle D'Aubigné-Postel scale provides limited information regarding pain, range of motion, stair climbing ability, and general function. It does not address knee stability or symptoms of patellofemoral disease such as pain with squatting or extended sitting, location of the pain, and general health measures.

In a retrospective study, Emmerson et al. (2007) evaluated the safety and effectiveness of osteochondral allograft transplantation for the treatment of osteochondritis dissecans of the femoral condyle. Sixty-six knees in 64 individuals underwent allografting, and each was evaluated both preoperatively and postoperatively using an 18-point modified D'Aubigné and Postel scale (higher scores indicating better range of motion) and by radiograph. The mean follow-up was 7.7 years (2 to 22) and the mean age was 28.6 years (15 to 54). All individuals had undergone previous surgery. Forty-one lesions involved the medial femoral condyle and 25 involved the lateral femoral condyle. All OCD were grade 3 or 4, based on the International Cartilage Repair Society (ICRS) classification system. The mean allograft size was 7.5 cm. One knee was lost to follow-up. Of the remaining 65 knees, 72% (n=47) were rated good/excellent, 11% (n=7) were rated fair, and 2% (n=1) were rated poor. Fifteen percent of individuals (n=10) underwent reoperation. The mean clinical score improved from 13.0 preoperatively to 16.4 postoperatively ($p < 0.01$). Ninety-two percent of individuals (n=59) completed questionnaires. Knee function improved from a mean of 3.4 to 8.4 on a 10-point scale ($p < 0.01$). The authors concluded that osteochondral allograft transplantation is a successful surgical treatment for osteochondritis dissecans of the femoral condyle. The study is limited in its small sample size, lack of a comparative group, and retrospective design.

In a review, Revell et al. (2009) examined the current available literature on osteochondral allograft transplantations. The authors noted that due to the many practical limitations associated with autogenic tissue use, investigators have turned to allogenic tissue as a possible means to generate successful cartilage tissue grafts. Due to the need for only one procedure, it is believed that allogenic grafts may be preferable. Clinical results of osteochondral allograft transplantation have demonstrated a high success rate ranging from 60% to 95% as defined by graft survival and good/excellent patient evaluations. Several clinical trials have indicated that individuals with unicompartmental traumatic arthritis have had a success rate of only 30%. In addition, other trials have demonstrated that allograft implantation was unsuitable for bipolar lesion repairs, with 50% of grafts failing 6 years after treatment when compared to an 84% success rate for unipolar grafts. Long-term follow-up of individuals receiving fresh osteochondral allografts revealed allograft survival rates of 95%, 80%. and 65% at 5, 10, and 15 years, respectively. The failure rate of allografts was higher among individuals with bipolar lesions as well as older individuals (e.g., 60 years and above). Due to the limited availability of fresh cadaveric tissue, several clinical studies have assessed the safety and effectiveness of frozen and cryo-preserved osteochondral allografts. Clinical results showed that

up to 70% of individuals reported good/excellent scores after transplantation, out to 4 years. Compared to fresh allografts, frozen allografts offer advantages including greater tissue availability, long time period for infectious disease testing, easier size matching, and a reduction in graft immunogenicity.

In a retrospective study, Lyon et al. (2012) evaluated the safety and effectiveness of osteochondral allograft transplantations in skeletally immature individuals who have failed conventional treatment. Eleven children with OCD of the knee were treated with a fresh, stored osteochondral allograft (6 males and 5 females). The average age of the children at the time of their allograft surgery was 15.2 years (13 to 20 years). Clinical assessment consisted of physical examination, radiography, magnetic resonance imaging (MRI), and a modified Merle D'Aubigné-Postel score. The size of the allograft was an average of 5.11 cm^2. Patients were followed for at least 12 months (average of 24 months; range between 12 and 41 months). All individuals returned to activities of daily living without difficulty at 6 months and returned to full sports activities between 9 and 12 months after surgery. Modified Merle D'Aubigné-Postel scores improved from an average of 12.7 preoperatively to 16.3 at 24 months postoperatively. Follow-up radiographs at 2 years showed full graft incorporation and no demarcation between the host and graft bone. The authors concluded that osteochondral allografts restored short-term function in individuals with juvenile osteochondral defects who have failed standard treatments. The study is limited in its small sample size, retrospective study design, lack of a comparative group, and short-term follow-up period, particularly in a pediatric study population.

In a retrospective study, Levy et al. (2012) evaluated the safety and effectiveness of osteochondral allograft transplantation and predictors of osteochondral allograft failure in 122 individuals representing 129 knees. Outcome measurements included pain and function (Knee Society function [KS-F], International Knee Documentation Committee [IKDC], and Merle D'Aubigné-Postel scores); frequency and types of reoperations; and graft survivorship. The mean age of the study participants was 33 years, and minimum follow-up was 2.4 years (median of 13.5 years). Ninety-one percent of individuals had more than 10 years of follow-up. Mean modified Merle D'Aubigné-Postel scores improved from 12.1 to 16, mean IKDC pain scores improved from 7.0 to 3.8, mean IKDC function score improved from 3.4 to 7.2, and KS-F scores improved from 65.6 to 82.5. Forty-seven percent of knees (n=61) underwent reoperations. Twenty-four percent of knees (n=31) failed at a mean of 7.2 years. Survivorship was 82% at 10 years, 74% at 15 years,

and 66% at 20 years. The authors concluded that having an age of more than 30 years at the time of surgery and having two or more previous surgeries for the operated knee were predictors associated with allograft failure. However, they also noted that follow-up of femoral condyle osteochondral allografting demonstrated durable improvement in pain and function, with graft survivorship of 82% at 10 years. The study is limited in its small sample size, retrospective study design, and lack of a comparative group.

In a prospective comparison study, Admad and Jones (2016) evaluated long-term clinical outcomes of using osteochondral autograft and allograft to manage either recurrent or large osteochondral lesions of the talas dome. This single center study evaluated 36 participants with large (1.5 cm^2; n=9) or recurrent cartilage lesions (volume >3.0 cm^3; n= 27) who either underwent osteochondral autograft (n=20) or osteochondral allograft plugs from a fresh donor talus (n=16). The trial primary outcomes were improvements in the Foot and Ankle Ability Measures (FAAM) and Visual Analog Scale pain scores. The FAAM and VAS score were similar between the two groups, allograft resulted in mean FAAM improvements of 55.2 to 80.7 and the mean VAS score reduction from 7.8 to 2.7. The autograft group reported mean improvement in FAAM of 54.4 to 85.5 and VAS score decreasing from 7.9 to 2.2. The allograft group was slightly less than that of the autograft, but the difference was not statistically significant. Both groups demonstrated significant improvements. Specific to the treatment of large lesions the comparison of 5 participants in the autograft and only 4 participants in the allograft limited the ability to produce comparison between the two treatment groups. The study is limited due to its dearth sample size.

In a recent systematic review, VanTienderen et al (2017) evaluated the current available literature on the use of fresh bulk osteochondral allograft transfer for the treatment of large osteochondral lesions of the talus. The authors included five from a possible 131 articles totaling 90 participants (91 ankles). The studies selected reported on at least one of the following primary outcomes of interest, which included functional outcome scores (American Orthopaedic Foot and Ankle Society [AOFAS], Foot Functional Index (FFI), pain visual analog scale (VAS) score, reoperation rate, or rate of allograft collapse. 74 participants in the review had at least one prior treatment (range, 1- 4). Lesions in the review had a mean volume of 3.7 cm^3 (1.0-10.9 cm^3) and study participants had a mean age of 39 years (range, 17-74). The five studies recorded follow-up for an average of 45 months and reported AOFAS scores improvements from 48 pretreatment to 80 postoperatively (range, 41-97; $p < .0005$). The mean VAS scored also demonstrated

significant improvements of 7.1 to 2.7 (range, 0-8; p < .0005). Four studies reported satisfaction scores, which resulted in a total 62 (70.5%) participants experiencing good to excellent outcomes. The review reported 23 (25.3%) participants required reoperation. The studies considered 12 (13.1%) participants to be treatment failures, as defined by postoperative graft nonunion or persistence of symptoms leading to arthrodesis or arthroplasty. The authors of the review report that the use of fresh bulk talar osteochondral allograft could significantly improve participant function and relieve pain caused from large osteochondral talar lesions.

SUMMARY

Osteochondral allograft transplantation appears to improve symptoms in select individuals who have had an inadequate response to a prior cartilage resurfacing procedure and are considered too young to be an appropriate candidate for total knee replacement or in select individuals with large osteochondral lesion of the talus, with or without an inadequate response to prior marrow stimulation when autografting may not be an option due to the lesion size, depth, or location. While there is a lack of comparative studies, long-term results of allograft transplantation appear promising. Based on the current available peer-reviewed literature, which is mainly retrospective in design, osteochondral allograft transplantation may be considered an option for symptomatic, skeletally mature individuals with unipolar cartilaginous defects of the femoral condyle or of the talar dome. In addition, the available evidence, clinical input, and recommendations from relevant medical societies indicate that osteochondral allograft transplantation has demonstrated some efficacy in individuals younger than 55 years of age with disabling knee pain and large or cystic lesions of the talus when autograft would be inadequate.

Considering the quality and availability of peer-reviewed literature, there are questions that still remain regarding the safety and effectiveness of osteochondral allograft treatment for the treatment of OCD of all other joints. Therefore, all other uses for OAT are considered experimental/ investigational and, not covered.

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-9, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)

MEDICALLY NECESSARY
27415, 29867

THE FOLLOWING CODE IS USED TO REPORT OPEN OR ARTHROSCOPIC REPAIR OF THE TALUS

WITH ALLOGRAFT
28899

Professional and outpatient claims with a date of service **on or before September 30, 2015, must be billed using ICD-9 codes. Professional and outpatient claims with a** date of service **on or after October 1, 2015, must be billed using ICD-10 codes.**

Facility/Institutional inpatient claims with a date of discharge **on or before September 30, 2015, must be billed with ICD-9 codes. Facility/Institutional inpatient claims with a** date of discharge **on or after October 1, 2015, must be billed with ICD-10 codes.**

ICD - 10 Procedure Code Number(s)

N/A

Professional and outpatient claims with a date of service **on or before September 30, 2015, must be billed using ICD-9 codes. Professional and outpatient claims with a** date of service **on or after October 1, 2015, must be billed using ICD-10 codes.**

Facility/Institutional inpatient claims with a date of discharge **on or before September 30, 2015, must be billed with ICD-9 codes. Facility/Institutional inpatient claims with a** date of discharge **on or after October 1, 2015, must be billed with ICD-10 codes.**

ICD -10 Diagnosis Code Number(s)

N/A

HCPCS Level II Code Number(s)

N/A

Revenue Code Number(s)

N/A

Misc Code

N/A:

Cross References

Policy: 05.00.08e: Continuous Passive Motion (CPM) Devices in the Home Setting

Policy: 11.14.03f: Meniscal Allograft Transplantation

Policy: 11.14.06i: Autologous Chondrocyte Implantation (ACI) and Other Cell-based Treatments of Focal Articular Cartilage Lesions

Policy: 11.14.09g: Osteochondral Autograft Transplantation (OAT) Procedure

Policy History

Revisions from 11.14.12e:

10/10/2018	The policy has been reviewed and reissued to communicate the Company's continuing position on Osteochondral Allograft Transplantation.

11.14.12e

01/02/2018	The policy has undergone a routine review, and the coverage position for osteochondral allograft transplantation of the talus for large or cystic lesions when autografting would be inadequate due to lesion size, depth, or location has been revised from experimental/investigational to medically necessary. Therefore, the following CPT code was added to the policy: THE FOLLOWING CODE IS USED TO REPORT OPEN OR ARTHROSCOPIC REPAIR OF THE TALUS WITH ALLOGRAFT 28899

Effective 10/05/2017 this policy has been updated to the new policy template format.

Version Effective Date: 01/02/2018
Version Issued Date: 01/02/2018
Version Reissued Date: 10/10/2018