BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Osteochondral Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Policy #: 248
Latest Review Date: May 2024
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Osteochondral Allografting

Blue Advantage will treat **osteochondral allografting** as a **covered benefit** when **used as a technique to repair** the following:

1. Full-thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (e.g., microfracture, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to size, location, or depth of the lesion
2. Large (area >1.5 cm2) or cystic (volume >3.0 cm3) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location.
3. Revision surgery after failed prior marrow stimulation for large (area >1.5 cm2) or cystic (volume >3.0 cm3) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth or location.

Blue Advantage will treat **osteochondral allografting for all other joints** as a **non-covered benefit** and as **investigational**.

Osteochondral Autografting

Blue Advantage will treat **osteochondral autografting**, **using one or more cores of osteochondral tissue** as a **covered benefit** and may be considered medically necessary for the following:

1. Treatment of symptomatic full-thickness cartilage defects of the knee caused by acute or repetitive trauma, in individuals who have had an inadequate response to a prior surgical procedure, when all of the following have been met.
    - Adolescent individuals should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult individuals 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 2.5cm2 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.
2. Large (area >1.5 cm2) or cystic (volume >3.0 cm3) osteochondral lesions of the talus.
3. Revision surgery after failed marrow stimulation for osteochondral lesion of the talus.

Blue Advantage will treat **osteochondral autografting for all other joints**, and any indications other than those listed above as a non-covered benefit and as investigational.

Blue Advantage will treat the treatment of **focal articular cartilage lesions with autologous minced or particulated cartilage** as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat the **treatment of focal articular cartilage lesions with allogeneic minced or particulated cartilage** as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **treatment of focal articular cartilage lesions with decellularized osteochondral allograft** (e.g., Chondrofix) as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **treatment of focal articular cartilage lesions with reduced osteochondral allograft discs** (e.g., ProChondrix, Cartiform) as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Osteochondral grafts are used in 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 in 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.

The following conclusions are based on a review of the evidence, including but not limited to published evidence and clinical expert opinion, solicited via BCBSA's Clinical Input Process.

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 2 main categories 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
Microfracture is an arthroscopic procedure in which a small pick creates a network of holes at the base of the articular cartilage lesion, allowing blood into the injured area to form clots and subsequent fibrocartilage growth. Mithoefer et al (2009) examined the efficacy of the microfracture technique for articular cartilage lesions of the knee in a systematic review. Twenty-eight studies (total N=3122 patients) were selected; 6 studies were randomized controlled trials (RCTs). 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 et al (2016) found that, at a mean of 12 years (range, 10-14) 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 have an effect on outcomes following marrow stimulation procedures.

Abrasion and Drilling
Abrasion and drilling are techniques to remove damaged cartilage. Instead of a drill, high speed burrs are used in the abrasion procedure.

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 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 and 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., 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 débridement 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 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 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 et al (2007) 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), 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). Reported knee problems were instability in daily activities, pain after walking 1 mile or more, slight limp, and difficulty squatting. Hangody et al (2001) 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 being investigated for cartilage repair. The Cartilage Autograft Implantation System (CAIS; Johnson and 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 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.

A minimally processed osteochondral allograft (Chondrofix®, Zimmer) has become available for use. Chondrofix® is composed of decellularized hyaline cartilage and cancellous bone and can be used "off the shelf" with precut cylinders (7-15mm). 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 (ACI) 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.

KEY POINTS:

This evidence review has been updated periodically with searches of the PubMed database. The most recent literature update was performed through February 27, 2023.

Summary of Evidence

The following conclusions are based on a review of the evidence, including but not limited to published evidence and clinical expert opinion, solicited via BCBSA's Clinical Input Process.

Knee Lesions

For individuals who have full-thickness articular cartilage lesions of the knee who receive osteochondral autografts, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and longer term observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Several systematic reviews have evaluated osteochondral autografting for cartilage repair in the short and mid-term. Compared to abrasion techniques (e.g., microfracture, drilling), there is evidence that osteochondral autografting decreases failure rates and improves outcomes in patients with medium-size lesions (e.g., 2-6 cm^2) when measured at longer follow-up. This is believed to be due to the higher durability of hyaline cartilage compared to fibrocartilage from abrasion techniques. There appears to be a relatively narrow range of lesion size for which osteochondral autografting is most effective. The best results have also been observed with lesions on the femoral condyles, although treatment of lesions on the trochlea and patella may also improve outcomes. Correction of malalignment is important for success of the procedure. The evidence suggests that osteochondral autografts may be considered an option for moderate-sized symptomatic full-thickness chondral lesions of the femoral condyle, trochlea, or patella. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have full-thickness articular cartilage lesions of the knee when autografting would be inadequate due to lesion size, location, or depth who receive fresh osteochondral allografts, the evidence includes case series and systematic reviews of case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Due to the lack of alternatives, this procedure may be considered a salvage operation in younger patients for full-thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (e.g., microfracture, osteochondral autografting, autologous chondrocyte implantation) would be inadequate due to lesion size, location, or depth. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Ankle Lesions

For individuals who have primary full-thickness articular cartilage lesions of the ankle less than 1.5 cm^2 who receive an osteochondral autograft, the evidence includes observational studies and systematic reviews of these studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A systematic review found similar improvements in outcomes following microfracture or autologous osteochondral transplantation (AOT). Another systematic review found that autologous osteochondral transplantation reduces pain and improves function in patients with osteochondral lesions of the talus, including lesions less than 1.5 cm^2; most included studies performed autologous osteochondral transplantation as a secondary procedure. Given the success of marrow stimulation procedures for smaller lesions (<1.5 cm^2) and the increase in donor-site morbidity with graft harvest from the knee, current evidence does not support the use of AOT as a primary treatment for smaller articular cartilage lesions of the ankle. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have large (area >1.5 cm^2) or cystic (volume >3.0 cm3) full-thickness articular cartilage lesions of the ankle who receive an osteochondral autograft, the evidence includes an RCT and several observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. An RCT in patients with large lesions found similar efficacy for AOT, marrow stimulation, and arthroplasty at 2-year follow-up. Longer term results were not reported in the RCT. However, observational studies with longer term follow-up (four to five years) have shown favorable results for patients with large or cystic lesions receiving osteochondral autograft transplantation. Limitations of the published evidence preclude determining the effects to the technology on health outcomes. Studies on the standard treatment for ankle lesions, marrow stimulation, have reported positive outcomes for patients with small lesions of the ankle (<1.5 cm^2) but have generally reported high failure rates for patients with large (>1.5 cm^2) lesions. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteochondral lesions of the ankle that have failed primary treatment who receive an osteochondral autograft, the evidence includes 2 nonrandomized comparative trials and several case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The best evidence for revision AOT comes from a nonrandomized comparative study that found better outcomes with AOT than with repeat marrow stimulation. This finding is supported by case series that have indicated good-to-

excellent results at mid-term and longer term follow-up with revision AOT. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. For individuals who have primary full-thickness articular cartilage lesions of the ankle less than 1.5 cm^2 who receive a fresh osteochondral allograft, there is little evidence. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Because microfracture is effective as a primary treatment for lesions less than 1.5 cm^2 and AOT is effective as a revision procedure, use of allograft for small primary cartilage lesions has not been reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have large (area >1.5 cm^2) or cystic (volume >3.0 cm3) cartilage lesions of the ankle when autografting would be inadequate who receive a fresh osteochondral allograft, the evidence includes a small number of patients in an RCT and systematic reviews of mainly case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The majority of patients in the RCT were patients with revision osteochondral lesions, so conclusions about the few patients with primary lesions could not be made. The systematic review of case series reported improvements in ankle scores and decreases in pain scores, though 25% of patients needed additional surgery and 13% experienced either graft nonunion, resorption, or symptom persistence in 1 systematic review. A recent systematic review compared allografts and autografts for osteochondral lesions of the talus, and found that talar osteochondral transplant using allografts was associated with higher rates of failure and revision compared with autografts at midterm follow-up. For particularly large lesions, marrow stimulation techniques have been found to be ineffective and obtaining an adequate volume of autograft may cause significant morbidity. For these reasons, osteochondral allografts may be a considered option for large lesions of the ankle. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have revision osteochondral lesions of the ankle when autografting would be inadequate who receive a fresh osteochondral allograft, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Most of the patients in the RCT had failed a prior microfracture. The RCT found that outcomes were statistically similar with osteochondral allografts compared with autografts. However, failure rates due to nonunion were higher in patients in the allograft group compared with patients in the autograft group. For particularly large lesions, marrow stimulation techniques have been found to be ineffective and obtaining an adequate volume of autograft may cause significant morbidity. For these reasons, osteochondral allografts may be a considered option for revision of large lesions of the ankle. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Elbow Lesions

For individuals who have full-thickness articular cartilage lesions of the elbow who receive an osteochondral autograft, the evidence includes a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Osteochondritis dissecans of the elbow typically occurs in patients who play baseball or do gymnastics. Although the meta-analysis suggested a benefit of osteochondral autographs compared to debridement or fixation, RCTs are needed to determine the effects of the procedure

with greater certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

Shoulder Lesions
For individuals who have full-thickness articular cartilage lesions of the shoulder who receive osteochondral autografts, the evidence includes a case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Evidence on osteochondral autografting for the shoulder is very limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

Knee, Ankle, Elbow, or Shoulder Lesions
For individuals who have full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder who receive autologous or allogeneic minced articular cartilage, the evidence includes a small RCT and small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on autologous minced cartilage includes 1 small RCT. The evidence on allogeneic juvenile minced cartilage includes a few small case series. The case series have suggested an improvement in outcomes compared with preoperative measures, but there is also evidence of subchondral edema, non-homogenous surface, graft hypertrophy, and delamination. For articular cartilage lesions of the knee, further evidence, preferably from RCTs, is needed to evaluate the effect on health outcomes compared with other procedures. There are fewer options for articular cartilage lesions of the ankle. However, further study in a larger number of patients is needed to assess the short- and long-term effectiveness of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder who receive decellularized osteochondral allograft plugs, the evidence includes small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The case series reported delamination of the implants, and high failure rates. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder who receive reduced osteochondral allograft discs, the evidence includes small case series. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. A prospective case series assessed ProChondrix for treatment of articular cartilage lesions of the knee and found sustained positive results out to a mean follow-up of 2.5 years, with a low failure rate. However, larger prospective studies with longer follow-up are necessary to further elucidate the safety and efficacy of reduced osteochondral allograft discs. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
American Orthopaedic Foot and Ankle Society
In 2022, The American Orthopaedic Foot and Ankle Society (AOFAS) issued a position statement on the use of osteochondral transplantation for the treatment of osteochondral lesions

of the talus. In the statement, the Society "endorses the use of osteochondral autograft and allograft transplantation for the treatment of osteochondral lesion of the talus, especially large diameter lesions, cystic lesions, and those that have failed previous surgical treatment. AOFAS does not consider these procedures to be experimental in a patient population that has failed nonoperative management."

International Consensus Group on Cartilage Repair of the Ankle
The International Consensus Group on Cartilage Repair of the Ankle (2017) convened to review the best available evidence and develop consensus statements to guide management of patients needing cartilage repair of the ankle. The Consensus Group, consisting of 75 experts from 25 countries, acknowledged that evidence in the field of cartilage repair of the ankle is both low-quality and at low-levels. One topic addressed by the Consensus Group was the use of osteochondral allografts. Through a process based on the Delphi method of achieving consensus, the following recommendations were issued:

- Osteochondral allograft plugs may be preferred over autografts in the following conditions: lesions >1.5 cm; knee osteoarthritis; history of knee infection; patients expressing concern of donor site morbidity of the knee. (grade of evidence: prospective cohort study)
- The source of osteochondral allograft plugs for the ankle should come from the ankle, not the knee. (grade of evidence: basic science)
- There is an absence of clinical evidence and clinical experience for the use of decellularized osteochondral allograft plugs.
- The preferred type of allograft for the ankle is fresh, nonfrozen. (grade of evidence: basic science).

American Academy of Orthopaedic Surgeons
In 2023, the American Academy of Orthopaedic Surgeons (AAOS)- released updated guidelines on the diagnosis and treatment of osteochondritis dissecans. In the guidelines, AAOS was unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature or mature patients with an unsalvageable osteochondritis dissecans lesion.

In 2010, an AAOS review of articular cartilage restoration methods states that “osteochondral autografting is generally used for smaller focal lesions of the femoral condyle no greater than 1.5 to 2 cm.”

National Institute for Health and Clinical Excellence
In 2018, the National Institute for Health and Care Excellence (NICE) issued a new guidance, mosaicplasty for symptomatic articular cartilage defects of the knee (IPG607). The guidance states that the evidence for safety and efficacy of mosaicplasty for knee cartilage defects is adequate to support the use of the procedure.

U.S. Preventive Services and Task Force Recommendations
Not Applicable.

KEY WORDS:
Osteochondral allograft transplantation, osteochondral autograft transplantation, OATS, OAT, mosaicplasty, articular cartilage, hyaline cartilage, fibrocartilage, CAIS, Chondrofix®, Neocartilage, DeNovo NT Graft, DeNovo® ET Graft, ProChondrix, Cartiform, AOT

APPROVED BY GOVERNING BODIES:
The U.S. Food and Drug Administration (FDA) 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. The 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.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT code:

27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (e.g. mosaicplasty) (includes harvesting of autograft[s])
28446	Open osteochondral autograft, talus (includes obtaining graft[s])
29866	Arthroscopy, knee, surgical: osteochondral autografts(s) (e.g., mosaicplasty) (includes harvesting of the autografts[s])
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)

There is no CPT code specific to osteochondral allograft of the talus.

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POLICY HISTORY:

Adopted for Blue Advantage, October 2005
Available for comment October 8-November 21, 2005
Medical Policy Group, September 2007
Medical Policy Group, July 2011
Available for comment July 21 through September 5, 2011
Medical Policy Group, July 2012
Medical Policy Group, May 2013
Medical Policy Group, June 2013
Available for comment July 9 through August 28, 2013
Medical Policy Group, September 2013
Medial Policy Group, June 2014
Available for comment July 9 through August 22, 2014
Medical Policy Group, June 2015
Available for comment July 1 through August 14, 2015
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Medical Policy Group, December 2016
Available for comment January 26 through March 11, 2017
Medical Policy Group, March 2017
Medical Policy Group, June 2017
Available for comment July 12 through August 27, 2017
Medical Policy Group, February 2018
Available for comment February 14 through March 30, 2018
Medical Policy Group, June 2018
Medical Policy Group, August 2019
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
Medical Policy Group, May 2020
Medical Policy Group, May 2021
Medical Policy Group. April 2022
Medical Policy Group, April 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, May 2024

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.