Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Policy # 00091
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions is addressed in medical policy number 00006.

Note: Meniscal Allografts and Other Meniscal Implants are addressed in medical policy number 00083.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Autograft or Autologous Mosaicplasty - Knee

Based on review of available data, the Company may consider osteochondral autograft transplant (OAT) or autologous mosaicplasty to treat cartilaginous defects of the knee to be **eligible for coverage****.

Patient Selection Criteria

Coverage eligibility for osteochondral autograft transplant (OAT) or autologous mosaicplasty to treat cartilaginous defects of the knee will be considered when **ALL** of the criteria listed below are met and no exclusion criteria are present (see exclusion criteria below):

- Size of cartilage defect is between 1.0 to 2.5 cm^2 total area, as documented by magnetic resonance imaging (MRI) or arthroscopy; **AND**
- Symptomatic, focal, full thickness (grade III or IV) isolated defect of the knee involving the weight bearing surface of the medial or lateral femoral condyles, trochlear or patellar region caused by acute or repetitive trauma; **AND**

- Age 15-55 years. Adolescent patients should be skeletally mature with documented closure of growth plates. Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive surgery, or when > 55 years of age must not have arthritis present on x-ray; **AND**
- Disabling localized knee pain present for at least three (3) months has failed to respond to at least 6 weeks of conservative treatment, unless a symptomatic loose body is present (See Policy Guidelines); **AND**
- Discrete lesion, single and unipolar (involving only one side of the joint – "kissing lesions" are not eligible for coverage), largely contained with near normal surrounding articular cartilage and articulating cartilage, (Outerbridge grades 0, 1, 2); **AND**
- Normal joint space present without evidence of inflammation or degenerative changes, and normal knee biomechanics, or alignment and stability achieved concurrently with osteochondral grafting; **AND**
- Patient is willing and able to comply with post-operative weight-bearing restrictions and rehabilitation.

Autograft or Autologous Mosaicplasty - Talus

Based on review of available data, the Company may consider either osteochondral autograft transplant (OAT) or autologous mosaicplasty to treat cartilaginous defects of the talus to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for either osteochondral autograft transplant (OAT) or autologous mosaicplasty to treat cartilaginous defects of the talus may be considered when **ALL** of the criteria listed below are met and no exclusion criteria are present (see exclusion criteria below):

- Skeletal maturity as documented by closure of growth plates; **AND**
- Disabling localized ankle pain present for at least 3 months has failed to respond to at least 6 weeks of conservative treatment, unless a symptomatic loose body is present; **AND**
- Individual is willing and able to comply with post-operative weight-bearing restrictions and rehabilitation; **AND**
- Lesion is discrete and single with near normal surrounding articular cartilage and articulating cartilage; **AND**
- Joint space is normal without evidence of inflammation or degenerative changes; **AND**

- Ankle joint is stable with functionally intact ligaments and normal alignment; **AND**
- One of the following are present:
  - Large (area >1.0 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the talus; **OR**
  - Revision surgery after failed marrow stimulation for osteochondral lesion of the talus.

Allograft – Knee

Based on review of available data, the Company may consider osteochondral allograft transplantation to treat cartilaginous defects of the knee to be **eligible for coverage****.

Patient Selection Criteria

Coverage eligibility for osteochondral allograft transplantation to treat cartilaginous defects of the knee will be considered when **ALL** of the criteria listed below are met and no exclusion criteria are present (see exclusion criteria below):

- Size of the cartilage defect is greater than or equal to 1.0 cm^2 total area, as documented by MRI or arthroscopy; **AND**
- Focal, full thickness, (grade III or IV) isolated defect of the knee involving the weight bearing surface of the medial or lateral femoral condyles or trochlear region caused by acute or repetitive trauma; **AND**
- Skeletal maturity as documented by closure of growth plates; **AND**
- Disabling localized knee pain present for at least three (3) months has failed to respond to at least 6 weeks of conservative treatment, unless a symptomatic loose body is present (See Policy Guidelines); **AND**
- When other cartilage repair techniques (e.g. microfracture, osteochondral autografting or autologous chondrocyte implantation [ACI]) would be inadequate due to lesion size, location, or depth; **AND**
- The knee is stable, with functionally intact menisci and ligaments and normal alignment; **AND**
- Discrete lesion, single and unipolar (involving only one side of the joint - kissing lesions" are not eligible for coverage), largely contained with near normal surrounding articular cartilage and articulating cartilage, (grades 0, 1, 2); **AND**
- Normal joint space present, without evidence of inflammation or degenerative changes; **AND**

- Patient is willing and able to comply with post-operative weight-bearing restrictions and rehabilitation.

Allograft - Talus

Based on review of available data, the Company may consider osteochondral fresh allograft transplantation to treat cartilaginous defects of the talus to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility may be considered for osteochondral fresh allograft transplantation to treat cartilaginous defects of the talus when **ALL** of the criteria listed below are met and no exclusion criteria are present (see exclusion criteria below):

- Skeletal maturity as documented by closure of growth plates; **AND**
- Disabling localized ankle pain present for at least 3 months has failed to respond to at least 6 weeks of conservative treatment, unless a symptomatic loose body is present; **AND**
- Individual is willing and able to comply with post-operative weight-bearing restrictions and rehabilitation; **AND**
- Lesion is discrete and single with near normal surrounding articular cartilage and articulating cartilage; **AND**
- Joint space is normal without evidence of inflammation or degenerative changes; **AND**
- Ankle joint is stable with functionally intact ligaments and normal alignment; **AND**
- **ONE** of the following are present:
    - Large (area >1.0 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; **OR**
    - Revision surgery after failed prior marrow stimulation for large (area >1.0 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.

Note: Corrective procedures, e.g., ligament or tendon repair, osteotomy for alignment, meniscal allograft transplant or repair, may be performed in combination with, or prior to, osteochondral transplantation.

Exclusion Criteria for Osteochondral Autograft and Allograft Transplantation

Coverage is not available for patients when **ANY** of the criteria listed below are present:

- Localized or systemic infection; **OR**
- Uncorrected misalignment and instability of the knee or ankle; **OR**
- Unstable knee or ankle and corrective procedure is not planned; **OR**
- History of malignancy in bones, cartilage, fat or muscle in the treated leg.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of osteochondral autografts/mosaicplasty and osteochondral allografts in the treatment of focal articular cartilage lesions when patient selection criteria are not met is considered **investigational.***

Based on review of available data, the Company considers the use of osteochondral autograft/mosaicplasty and osteochondral allograft transplantation for joints other than those listed above, to be **investigational.***

Based on review of available data, the Company considers **ALL** of the following treatments for focal articular cartilage lesions to be **investigational*:**

- Autologous or allogeneic minced or particulated cartilage (e.g., DeNovo NT Graft®‡, BioCartilage®‡);
- Decellularized osteochondral allograft plugs (e.g., Chondrofix) and other cell-free implants, including but not limited to biodegradable hydroxyapatite/aragonite implant (e.g., Agili-C);
- Reduced osteochondral allograft discs (e.g., ProChondrix, Cartiform);
- Non-autologous mosaicplasty with resorbable synthetic bone filler materials, including, but not limited to, plugs and granules to repair osteochondral defects of the knee or ankle;
- Allografts preserved by nonstandard tissue bank methods (e.g., Missouri Osteochondral Allograft Preservation System);
- Use of larger allografts that involve removing and replacing half or more of the articular surfaces of the knee as an alternative to traditional total joint replacement (e.g., hemi condylar or total condylar for degenerative conditions).

Policy Guidelines

Conservative management

In the majority of cases, a period of conservative management is appropriate prior to intervention. Conservative management[1] must include a combination of strategies to reduce inflammation, alleviate pain, and correct underlying dysfunction, including physical therapy **AND** at least **ONE** complementary conservative treatment strategy.

Physical therapy requirement includes **ANY** of the following:

- Physical therapy rendered by a qualified provider of physical therapy services; **OR**
- Supervised home exercise program that includes **ALL** of the following:
  - Participation in a patient-specific or tailored program; **AND**
  - Initial active instruction by MD/DO/PT with redemonstration of patient ability to perform exercises; **AND**
  - Compliance (documented or by clinician attestation on follow-up evaluation);

OR

- Exception to the physical therapy requirement in unusual circumstances (for instance intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record.

Complementary conservative treatment requirement includes **ANY** of the following:

- Anti-inflammatory medications and analgesics; **OR**
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants; **OR**
- Intraarticular corticosteroid injection(s)[1]; **OR**
- Alternative therapies such as activity modification, and/or a trial period of rest (e.g., from the aggravating/contributing factors) where applicable.

[1] In the absence of contraindications.

Clinical reevaluation. In most cases, reevaluation should include a physical examination. Direct contact by other methods, such as telephone communication or electronic messaging, may substitute for in-person evaluation when circumstances preclude an office visit. Clinical

reevaluation must be done in reasonable proximity to the anticipated date of service such that the patient's condition would be unlikely to change by the date of service.

Failure of conservative management requires **ALL** of the following:

- Patient has completed a full course of conservative management (as defined above) for the current episode of care; **AND**
- Worsening or of no significant improvement in signs and/or symptoms upon clinical reevaluation; **AND**
- More invasive forms of therapy are being considered.

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate.

Background/Overview

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 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: debridement (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 microfracture, abrasion arthroplasty, 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 (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. Solheim et al (2016) reported on a prospective longitudinal study of 110 patients and 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 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 are 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. However, 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 & Nephew), the OATS (Osteochondral Autograft Transfer System; Arthrex), and the COR and COR2 systems (DePuy Mitek). Although mosaicplasty and autologous osteochondral transplantation may use different instrumentation, the underlying mode of repair is similar (ie, 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 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 autologous osteochondral transplantation 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, the 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 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 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 autologous osteochondral transplantation.

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 (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 autologous osteochondral transplantation 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.

Agili-C (CartiHeal) is a cell-free aragonite-based scaffold with dual mechanism of action, promoting bone marrow-derived stem cells adhesion and differentiation into chondrocytes by calcium carbonate in the aragonite crystalline form combined with cartilage cells migration from the surrounding native cartilage, their proliferation and deposition of extra-cellular matrix. In 2016, a

comparative clinical study of cylindric versus tapered design of the Agili-C plug showed equal positive clinical benefits at 12 months, but a clear advantage in revision rate for the tapered Agili-C plug with 0% revision rate. The mean defect size was 2.5 cm^2 and with a small cohort with a mean age of 31 years old more than 75% defect fill was shown in 84% of the cases. Authors of 2022 literature review noted that although the sample size was very small, the Agili-C might be feasible as a biological unicondylar prosthesis. Because of limited clinical studies available in the literature, complications and failure rates could not be found. The study in Italy including 150 participants has not yet published the results of its long-term follow-up.

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 techniques are discussed in medical policy 00006.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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. The Food and Drug Administration 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.

Agili-C (CartiHeal Ltd.) was approved for marketing in March 2021. The implant is made from natural calcium carbonate found in the purified external skeleton of coral, is biocompatible and biodegradable. The Agili-C is intended for use at the site of cartilage or osteochondral defects of the knee joint when that damage is caused by trauma or by osteoarthritis. It is used for injuries to the surface of the knee joint that are considered grade 3 or above based on the International Cartilage Repair Society measurement.

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

Osteochondral grafts are used to repair full-thickness chondral defects involving a joint. In the case of osteochondral autografts, 1 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.

Summary of Evidence

Knee Lesions

For individuals who have full-thickness articular cartilage lesions of the knee who receive an osteochondral autograft, 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 with abrasion techniques (eg, microfracture, drilling), there is evidence that osteochondral autografting decreases failure rates and improves outcomes in patients with medium-size lesions (eg, 2-6 cm^2) when measured at longer follow-up. This is believed to be due to the higher durability of hyaline cartilage compared with 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 the 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 a fresh osteochondral allograft, 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 (eg, 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 and autologous osteochondral transplantation. 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 autologous osteochondral transplantation as a primary treatment for smaller articular cartilage lesions of the ankle. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) full-thickness articular cartilage lesions of the ankle who receive an osteochondral autograft, the evidence includes a RCT and several observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A RCT in patients with large lesions found similar efficacy for autologous osteochondral transplantation, 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 (4-5 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 of 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 autologous osteochondral transplantation comes from a nonrandomized comparative study that found better outcomes with autologous osteochondral transplantation 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 autologous osteochondral transplantation. 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 autologous osteochondral transplantation is effective as a revision procedure, use of allograft for small primary cartilage lesions has not been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) 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 a 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 reviews 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 a 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 an 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 with debridement or fixation, RCTs are needed to determine the effects of the procedure with greater certainty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Shoulder Lesions
For individuals who have full-thickness articular cartilage lesions of the shoulder who receive an osteochondral autograft, 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 that the technology results in an improvement in the net health outcome.

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 or particulated 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 a 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, nonhomogeneous 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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, quality of life, 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 that the technology results in an improvement in the net health outcome.

Supplemental Information

2017 Input

In response to requests, clinical input on osteochondral autografts for treating focal articular cartilage lesions in the ankle and elbow was received from 3 respondents, including 2 specialty society-level responses and 1 physician from 1 health system, while this policy was under review in 2017.

Input obtained in 2017 supports the following indications:

- Use of osteochondral autograft for:
  - Primary treatment of large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesion of the talus.
  - Revision surgery after failed marrow stimulation for osteochondral lesion of the talus.
- Use of fresh osteochondral allograft for:
  - Primary treatment of large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesion of the talus when autografting would be inadequate due to lesion size, depth, or location.
  - Revision surgery for osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location.

Thus, the above indications may be considered medically necessary considering the suggestive evidence and clinical input support.

However, the clinical input does not support whether the following indication provides a clinically meaningful improvement in the net health outcome or is consistent with generally accepted medical practice.

- Use of osteochondral grafts in the elbow.

Thus, the above indication may be considered investigational.

2011 Input

In response to requests, input was received from 3 academic medical centers while this policy was under review in 2011. Input generally agreed with the stated criteria for osteochondral grafting, except the following: Input was mixed on the requirement for an inadequate response to a prior surgical procedure, the size of the lesion, and the requirement for an absence of meniscal pathology.

Input was also mixed on the investigational status of osteochondral grafts in other joints, including the patellar and talar joints, and for the use of autologous minced cartilage.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Ankle

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
In 2017, the International Consensus Group on Cartilage Repair of the Ankle 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, not frozen. (grade of evidence: basic science)

Elbow

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 stated that "osteochondral autografting is generally used for smaller focal lesions of the femoral condyle no greater than 1.5 to 2 cm."

Knee

National Institute for Health and Care Excellence
In 2018, the National Institute for Health and Care Excellence issued a new guidance on 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 Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

Ongoing			
NCT03873545[a]	A Prospective, Multi-Center Study Evaluating ProChondrix®‡ CR for the Repair of Focal Articular Cartilage Defects in the Knee	34	Dec 2026
NCT05391841[a]	Prospective, Non-interventional Study to Evaluate the Efficacy and Safety of NOVOCART Inject for the Treatment of Cartilage Defects in the Knee in Pediatric Patients With Closed Epiphyses	30	May 2032
NCT04744402[a]	A Multi-Center, Active-Controlled, Open-Label, Phase 2 Trial to Compare the Efficacy and Safety of CartiLife®‡, and Microfracture for Patients With Articular Cartilage Defects in the Knee	25	Dec 2023
NCT04296487	Introduction of Autologous Chondrocyte Implantation Procedure for the Treatment of Chondral Defect in the Knee	100	Sep 2025
NCT03219307[a]	Safety and Efficacy of NOVOCART 3D in the Treatment of Articular Cartilage Defects Following Failure on Microfracture	30	Dec 2028
Unpublished			
NCT01656902[a]	A Prospective Randomized Controlled Multicenter Phase-III Clinical Study to Evaluate the Safety and Effectiveness of NOVOCART®‡ 3D Plus Compared to the Standard Procedure Microfracture in the Treatment of Articular Cartilage Defects of the Knee	263	Jun 2023 (completed)

NCT01329445[a]	Post Market, Longitudinal Data Collection Study of DeNovo NT for Articular Cartilage Defects of the Knee	160	Dec 2021 (unknown)
NCT01670617[a]	A Stratified, Post-Market Study of DeNovo NT for the Treatment of Femoral and Patellar Articular Cartilage Lesions of the Knee	90	Dec 2021 (unknown)
NCT01347892[a]	Post Market, Longitudinal Data Collection Study of Articular Cartilage Lesions in the Ankle Treated With DeNovo(R) NT	205	Sep 2019 (unknown)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

Original Effective Date: 08/26/2002
Current Effective Date: 11/01/2024

07/18/2002	Medical Policy Committee review
08/26/2002	Managed Care Advisory Council approval
08/31/2004	Medical Director review
09/21/2004	Medical Policy Committee review. Format revision. No substance change to policy.
09/27/2004	Managed Care Advisory Council approval
12/07/2004	Medical Director review
12/14/2004	Medical Policy Committee review. Coverage eligibility criteria revisions. Policy expanded to address osteochondral allografts as well as Osteochondral autografts.
01/31/2005	Managed Care Advisory Council approval
02/01/2006	Medical Director review
02/15/2006	Medical Policy Committee review
02/23/2006	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. No change to coverage eligibility.
04/02/2008	Medical Director review
04/16/2008	Medical Policy Committee approval. No change to coverage eligibility.
04/02/2009	Medical Director review
04/15/2009	Medical Policy Committee approval. No change to coverage eligibility.
04/08/2010	Medical Director review
04/21/2010	Medical Policy Committee approval. No change to coverage eligibility.
04/07/2011	Medical Policy Committee approval

04/13/2011 Medical Policy Implementation Committee approval. No change to coverage eligibility.
04/12/2012 Medical Policy Committee review
04/25/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/04/2013 Medical Policy Committee review
04/24/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2014 Medical Policy Committee review
04/23/2014 Medical Policy Implementation Committee approval. Investigational statements added on autologous and allogeneic minced cartilage.
09/03/2015 Medical Policy Committee review
09/23/2015 Medical Policy Implementation Committee approval. Added defect of patella area to eligibility criteria for osteochondral autografting. Title change.
11/03/2016 Medical Policy Committee review
11/16/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
02/02/2017 Medical Policy Committee review
02/15/2017 Medical Policy Implementation Committee approval. Patient age limit in criteria changed from 50 to 55. Investigational statements added for decellularized osteochondral allograft plugs (eg, Chondrofix) and reduced osteochondral allograft discs (eg, ProChondrix, Cartiform).
02/01/2018 Medical Policy Committee review
02/21/2018 Medical Policy Implementation Committee approval.
For autograft or autologous mosaicoplasty of the knee, criteria loosened to align with AIM Guidelines as follows:

- Persistent symptoms of disabling localized knee pain for at least three (3) months, which has failed to respond to conservative treatment.

Added a *"Note"* regarding corrective procedures following allograft of the knee.
Added autograft and allograft of the talus to be eligible for coverage with criteria.
For allograft of the knee, criteria changes made to align with AIM Guidelines as follows :

- Size of the cartilage defect is greater than or equal to 2 cm^2 total area, as documented by MRI or arthroscopy;
- Skeletal maturity as documented by closure of growth plates;
- Persistent symptoms of disabling localized knee pain for at least three (3) months, which has failed to respond to conservative treatment;
- Normal joint space present, without evidence of inflammation or degenerative changes.

Exclusion criteria revised and exclusion subtitle is specified for autografts and allografts of the knee.
Removed "the ankle (talus)" from the investigational statement for the use of osteochondral autograft/mosaicplasty and osteochondral allograft transplantation for joints other than the knee to expand coverage eligibility.

02/07/2019 Medical Policy Committee review
02/20/2019 Medical Policy Implementation Committee approval. Added "or particulated" to the investigational policy statements on minced cartilage. Added a Policy Guidelines section addressing conservative management from AIM Guidelines.
02/06/2020 Medical Policy Committee review
02/12/2020 Medical Policy Implementation Committee approval. Revised eligible for coverage criteria for autograft or autologous mosaicplasty of the knee and allograft of the knee to include conservative treatment to be tried and failed for a minimum 6 weeks as follows: "persistent symptoms of disabling localized knee pain for at least three (3) months, which has failed to respond to conservative treatment tried for a minimum of 6 weeks". Updated conservative management information in the Policy Guidelines to track AIM Guidelines.
09/10/2020 Coding update
02/04/2021 Medical Policy Committee review
02/10/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/03/2022 Medical Policy Committee review
02/09/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Revised Policy Guidelines section to track AIM Guidelines.
02/16/2022 Post MPIC, an administrative correction was made that does not change coverage intent. Removed "and osteochondral allografts" from the coverage statement with

	criteria for **Autograft or Autologous Mosaicplasty – Knee** for clarification. There is a separate coverage section with criteria for **Allograft – Knee.**
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Revisions to coverage section and Policy Guidelines section track AIM Guidelines.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Added "…and other cell-free implants, including but not limited to biodegradable hydroxyapatite/aragonite implant (e.g., Agili-C)" to the investigational statement for treatment of focal cartilage lesions with decellularized osteochondral allograft plugs.
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. All revisions track Carelon Guidelines. Autograft or autologous mosiacplasty of the knee criteria bullet revised for disabling localized knee pain. Added criteria for autograft and allograft mosiacplasty of the talus, including cartilaginous defects of the talus criteria changed to an area >1.0 cm2. Allograft of the knee criteria for size of cartilage defect changed to 1.0 cm 2. Allograft of the talus criteria added. Revised investigational statements to list in bulleted format and add new exclusions to this list. Added examples of minced or particulated cartilage (e.g., DeNovo NT Graft®‡, BioCartilage®‡) to the investigational treatments for focal articular cartilage lesions. Revisions made to Policy Guidelines.

Next Scheduled Review Date: 09/2024

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	27415, 27416, 28446, 29866, 29867 Delete code effective 08/01/2023: 20932 Add codes effective 11/01/2024: 20932, 20933, 20934
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally 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, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Policy # 00091
Original Effective Date: 08/26/2002
Current Effective Date: 11/01/2024

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.