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MEDICAL POLICY – 7.01.78

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

BCBSA Ref. Policy:	7.01.78		
Effective Date:	July 1, 2024	RELATED MEDICAL POLICIES:	
Last Revised:	June 10, 2024	7.01.15	Meniscal Allografts and Other Meniscal Implants
Replaces:	7.01.570	7.01.48	Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions
		11.01.524	Site of Service: Select Surgical Procedures

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Cartilage is tissue that covers the ends of bones where they come together to form joints. Cartilage allows the ends of the bones to move comfortably across each other as a joint flexes or rotates. A focal articular cartilage lesion is an area of damage to cartilage and possibly the bone beneath it. When cartilage is damaged, over time it can deteriorate to the point where all of the cartilage is worn away and the bone beneath is affected. This is known as a full thickness defect. Grafting a small amount of bone and cartilage is one way to treat severe or large areas of damage. The graft material can be taken from a person's own tissue (this is known as an autograft) or from donor tissue (allograft). This policy discusses when cartilage grafting may be considered medically necessary. There are a number of other methods of using cartilage tissue to repair damage. This includes cutting cartilage into tiny pieces and placing it over the damaged area. These and other similar techniques are unproven and not covered.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a

service may be covered.

Policy Coverage Criteria

We will review for medical necessity these elective surgical procedures.

We also will review the site of service for medical necessity. Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

Site of Service for Elective Surgical Procedures	Medical Necessity
Medically necessary sites of service: • **Off campus-outpatient hospital/medical center** • **On campus-outpatient hospital/medical center** • **Ambulatory Surgical Center**	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost- effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.**

Inpatient hospital/medical center	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the individual has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):**
	• Anesthesia Risk
	  ○ ASA classification III or higher (see **definition**)
	  ○ Personal history of complication of anesthesia
	  ○ Documentation of alcohol dependence or history of cocaine use
	  ○ Prolonged surgery (>3 hours)
	• Cardiovascular Risk
	  ○ Uncompensated chronic heart failure (**NYHA class** III or IV)
	  ○ Recent history of myocardial infarction (MI) (<3 months)

Site of Service for Elective Surgical Procedures	Medical Necessity
	○ Poorly controlled, resistant hypertension* ○ Recent history of cerebrovascular accident (< 3 months) ○ Increased risk for cardiac ischemia (drug eluting stent placed < 1 year or angioplasty <90 days) ○ Symptomatic cardiac arrhythmia despite medication ○ Significant valvular heart disease • Liver Risk ○ Advance liver disease (MELD Score > 8)** • Pulmonary Risk ○ Chronic obstructive pulmonary disease (COPD) (FEV1 <50%) ○ Poorly controlled asthma (FEV1 <80% despite treatment) ○ Moderate to severe obstructive sleep apnea (OSA)*** • Renal Risk ○ End stage renal disease (on dialysis) • Other ○ Morbid obesity (BMI ≥ 50) ○ Pregnancy ○ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criterion]) ○ Anticipated need for transfusion(s) **Note**: * 3 or more drugs to control blood pressure ** https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease *** Moderate-AHI≥15 and ≤ 30, Severe-AHI ≥30 ****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)
Inpatient hospital/medical center	**This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.**

Treatment	Medical Necessity
Osteochondral allografting	**Fresh osteochondral (human cadaver tissue) allografting may be considered medically necessary as a technique to repair:** • Full-thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (e.g., microfracture, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to lesion size, location, or depth. • Large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location. • Revision surgery after failed prior marrow stimulation for large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth or location **Osteochondral allografting for all other joints is considered investigational.**

Osteochondral autografting	**Osteochondral autografting, using one or more cores of osteochondral tissue, may be considered medically necessary:**
	• For the treatment of symptomatic full-thickness cartilage defects of the knee caused by acute or repetitive trauma in 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). Adult individuals should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., ≤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 1.0 and 2.5 cm^2 in size
	  ○ Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less) and normal-appearing hyaline cartilage surrounding the border of the defect
	  ○ Normal knee biomechanics or alignment and stability achieved concurrently with osteochondral grafting.

Treatment	Medical Necessity
	• Large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the talus • Revision surgery after failed marrow stimulation for osteochondral lesion of the talus. **Osteochondral autografting for all other joints and any indications other than those listed above is considered investigational.**

Treatment	Investigational
Treatment of focal articular cartilage lesions	**Treatment of focal articular cartilage lesions with autologous minced or particulated cartilage (e.g., the Cartilage Autograft Implantation System (CAIS), the Reveille Cartilage Processor) is considered investigational.** **Treatment of focal articular cartilage lesions with allogeneic minced or particulated cartilage (e.g., BioCartilage, DeNovo Natural Tissue (NT) Graft) is considered investigational.** **Treatment of focal articular cartilage lesions with decellularized osteochondral allograft plugs (e.g., Chondrofix) is considered investigational.** **Treatment of focal articular cartilage lesions with reduced osteochondral allograft discs (e.g., ProChondrix, Cartiform) is considered investigational.**

Additional Information
• If débridement is the only prior surgical treatment, consideration should be given to marrow-stimulating techniques before osteochondral grafting is performed, particularly for lesions less than 1.5 cm^2 in area or 3.0 cm^3 in volume. • Severe obesity (e.g., body mass index >35 kg/m^2) may affect outcomes due to the increased stress on weight-bearing surfaces of the joint. • Misalignment and instability of the joint are contraindications. Therefore, additional procedures, such as repair of ligaments or tendons or creation of an osteotomy for

Additional Information

realignment of the joint, may be performed at the same time. In addition, meniscal allograft transplantation may be performed in combination, either concurrently or sequentially, with osteochondral allografting or osteochondral autografting.

Documentation Requirements

The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Conservative care attempted with length of time attempted
- Pertinent imaging reports
- If procedure is planned as inpatient, indications supporting need for inpatient procedure

Coding

Code	Description
CPT	
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 autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft[s])
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

American Society of Anesthesiologists (ASA) Score:

ASA 1 A normal healthy patient.
ASA 2 A patient with mild systemic disease.
ASA 3 A patient with severe systemic disease.
ASA 4 A patient with severe systemic disease that is a constant threat to life.
ASA 5 A moribund patient who is not expected to survive.

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Table 1. Outerbridge Classification

Grade	Pathology
0	Normal cartilage
I	Softening and swelling of articular cartilage
II	Fragmentation and fissuring of articular cartilage affecting an area of less than 0.5 inches
III	Fragmentation and fissuring of articular cartilage affecting an area of greater than 0.5 inches
IV	Cartilage erosion to bone

Consideration of Age

The age range listed in this policy, 15 or older to 55 years of age, takes into consideration skeletal maturity and the age at which total knee replacements are considered. Skeletal maturity is reached in adolescence, and adults younger than 55 are generally considered unsuitable candidates for total knee replacement.

Description

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

Background

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.[1] Talar lesions are reported to be about 4% of osteochondral lesions.[2]

Treatment

There are two main goals of conventional therapy for individuals 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 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.[3] Twenty-eight studies (total N=3122 individuals) were selected; six 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. Solheim et al (2016) reported on a prospective longitudinal study of 110 individuals and found that, at a mean of 12 years (range, 10-14) after microfracture, 45.5% of individuals had poor outcomes, including 43 individuals who required additional surgery.[4] 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 individuals 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 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 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 individuals who had undergone graft harvest from the knee (mean, 2.9 plugs) for treatment of osteochondral lesions of the talus.[5] At an average 47-month follow-up (range, 7-77), 5 individuals 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 one mile or more, slight limp, and difficulty squatting. Hangody et al (2001) reported that some individuals 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 individuals evaluated 2 to 7 years after autologous osteochondral transplantation.[6]

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 & 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 two years. The osteochondral discs are typically inserted after microfracture and secured in place with fibrin glue and/or sutures.

Autologous chondrocyte implantation is another method of cartilage repair involving the harvesting of normal chondrocytes from normal non-weight-bearing articular surfaces, which are then cultured and expanded in vitro and implanted back into the chondral defect. Autologous chondrocyte implantation techniques are discussed in a separate medical policy (see **Related Policies**).

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 (e.g., microfracture, drilling), there is evidence that autologous osteochondral autografting decreases failure rates and improves outcomes in individuals 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 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 success of the procedure. The evidence suggests that osteochondral autografting 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 individuals 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 and autologous osteochondral transplantation. Another systematic review found that autologous osteochondral transplantation reduces pain and improves function in individuals with osteochondral lesions of the talus, including lesions less than 1.5 cm2; 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 an RCT and several observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. An RCT in individuals with large lesions found similar efficacy for autologous osteochondral transplantation, marrow stimulation, and arthroplasty at two-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 individuals 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 individuals with small lesions of the ankle (<1.5 cm^2) but have generally reported high failure rates for individuals 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 two 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 individuals 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 individuals in the RCT were individuals with revision osteochondral lesions, so conclusions about the few individuals 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 individuals needed additional surgery and 13% experienced either graft nonunion, resorption, or symptom persistence in one 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. 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 individuals 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 individuals in the allograft group compared with individuals 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 individuals who play baseball or do gymnastics. Although the meta-analysis suggested a benefit of osteochondral autographs compared with débridement 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 outcomes.

Shoulder Lesions

For individuals who have full-thickness articular cartilage lesions of the shoulder who receive an autologous 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, nonhomogenous 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 individuals 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.

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
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	25	Dec 2023

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Microfracture for Patients With Articular Cartilage Defects in the Knee		
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

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2017 Input

In response to requests, clinical input on osteochondral autografts improves for treating focal articular cartilage lesions in the ankle and elbow was received from three respondents, including two specialty society-level response and one physician from one 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 three 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

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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.[82] 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.[83] 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.[84]

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."[85]

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).[86] 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.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The US 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 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.

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History

Date	Comments
08/01/20	New policy, approved July 14, 2020. Policy replaces 7.01.570. Policy updated with literature review through February 11, 2020; no references added. Policy statements unchanged.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through March 5, 2021; references added. Policy statements unchanged.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through March 8, 2022; references added. Policy statements unchanged.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through February 27, 2023; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
08/01/23	Minor update to Related Policies. Removed 7.01.569 and replaced with 7.01.48 Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through February 28, 2024; no references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.