Protocol

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

(70178)

Medical Benefit		**Effective Date**: 10/01/17	**Next Review Date**: 07/18
Preauthorization	No	**Review Dates**: 03/07, 05/08, 03/09, 01/10, 01/11, 09/11, 09/12, 09/13, 07/14, 07/15, 07/16, 07/17	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With full-thickness articular cartilage lesions of the knee	Interventions of interest are: • Osteochondral autograft	Comparators of interest are: • Débridement • Marrow stimulation procedures • Autologous chondrocyte implantation	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With full-thickness articular cartilage lesions of the knee	Interventions of interest are: • Osteochondral allograft	Comparators of interest are: • Débridement • Marrow stimulation procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With full-thickness articular cartilage lesions of the ankle	Interventions of interest are: • Osteochondral autograft	Comparators of interest are: • Débridement • Marrow stimulation procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With full-thickness articular cartilage lesions of the ankle	Interventions of interest are: • Osteochondral allograft	Comparators of interest are: • Débridement • Marrow stimulation procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With full-thickness articular cartilage lesions of the elbow	Interventions of interest are: • Osteochondral autograft	Comparators of interest are: • Débridement • Marrow stimulation procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With full-thickness articular cartilage lesions of the shoulder	Interventions of interest are: • Osteochondral autograft	Comparators of interest are: • Débridement • Marrow stimulation procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder	Interventions of interest are: • Autologous or allogeneic minced articular cartilage	Comparators of interest are: • Débridement • Marrow stimulation procedures • Autologous chondrocyte implantation	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder	Interventions of interest are: • Decellularized osteochondral allograft plugs	Comparators of interest are: • Débridement • Marrow stimulation procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder	Interventions of interest are: • Reduced osteochondral allograft discs plugs	Comparators of interest are: • Débridement • Marrow stimulation procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

Description

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

Summary of Evidence

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

For individuals who have full-thickness articular cartilage lesions of the knee who receive osteochondral allografts, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Due to the lack of alternatives, this procedure may be considered a salvage

operation in younger patients for full-thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (e.g., microfracture, osteochondral autografting, autologous chondrocyte implantation) would be inadequate due to the size, location, or depth of the lesion. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have full-thickness articular cartilage lesions of the ankle who receive osteochondral autografts, the evidence includes one small RCT, observational studies, and a systematic review of these studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review and an RCT found similar improvements in outcomes after microfracture or osteochondral autografting. Given the lack of established benefit compared to microfracture and the increase in donor-site morbidity with graft harvest from the knee, evidence does not support the use of osteochondral autografts as a primary treatment for articular cartilage lesions of the ankle. There are some observational studies in patients who have a failed a prior surgical procedure. Further study in prospective trials is needed to evaluate outcomes for osteochondral autografting as a secondary procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the ankle who receive osteochondral allografts, the evidence includes one case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. These series have indicated high failure rates. The largest had a failure rate of nearly 30% with revision to a second allograft, ankle arthroplasty, fusion, or amputation. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the elbow who receive osteochondral autografts, the evidence includes a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Osteochondritis dissecans (OCD) of the elbow typically occurs in patients who play baseball or do gymnastics. The literature on osteochondral autografts for advanced OCD of the elbow consists of small case series, primarily from Europe and Asia, and a systematic review of case series. Although the meta-analysis suggested a benefit of osteochondral autographs compared to débridement or fixation, RCTs are needed to determine the effects of the procedure with greater certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder who receive autologous or allogeneic minced articular cartilage, the evidence includes a small RCT and small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on autologous minced cartilage includes one small RCT from 2011. 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 graft hypertrophy and delamination. For articular cartilage lesions of the knee, further evidence, preferably from RCTs, is needed to evaluate the effect on health outcomes compared with other procedures. There are fewer options for articular cartilage lesions of the ankle. However, further study in a larger number of patients is needed to assess the short- and long-term effectiveness of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder who receive decellularized osteochondral allograft plugs or reduced osteochondral allograft discs, the evidence includes one small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and

treatment-related morbidity. The single case series on decellularized osteochondral allograft plugs reported delamination of the implants, and high failure rates. No studies have been identified on reduced osteochondral allograft discs. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Osteochondral allografting may be considered **medically necessary** as a technique to repair full-thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (e.g., microfracture, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to the size, location, or depth of the lesion.

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

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 patients who have had an inadequate response to a prior surgical procedure, when all of the following have been met:

- Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years).
- Focal, full thickness (grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles, trochlea, or patella that are between one 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.

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

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

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

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**.

Policy Guidelines

If debridement is the only prior surgical treatment, consideration should be given to marrow-stimulating techniques before osteochondral grafting is performed.

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

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

time. In addition, meniscal allograft transplantation may be performed in combination, either concurrently or sequentially, with osteochondral allografting or osteochondral autografting.

Background

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. 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 grafts chondrocytes retain features of hyaline cartilage that is similar in composition and property to the original articulating surface of the joint. If true, the restoration of a hyaline cartilage surface might restore the integrity of the joint surface and promote long-term tissue repair, thereby improving function and delaying or preventing further deterioration.

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

First, there are procedures intended to primarily achieve symptomatic relief: débridement (removal of debris and diseased cartilage); lavage (saline washout); 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 include: abrasion arthroplasty, microfracture, and drilling, all of which are considered standard therapies. 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.

Efficacy of the microfracture technique was examined in a 2009 systematic review.[1] Twenty-eight studies (total N=3122 patients) 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. A prospective longitudinal study of 110 patients by Solheim et al (2016) 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.[2]

Both fresh and cryopreserved allogeneic osteochondral grafts have been used with some success, although cryopreservation decreases the viability of cartilage cells, and fresh allografts may be difficult to obtain and create concerns regarding infectious diseases. As a result, autologous osteochondral grafts have been investigated as an option to increase the survival rate of the grafted cartilage and to eliminate the risk of disease transmission. Autologous grafts are limited by the small number of donor sites; thus allografts are typically used for larger lesions. In an effort to extend the amount of the available donor tissue, investigators have used multiple, small osteochondral cores harvested from non-weight-bearing sites in the knee for treatment of full-thickness chondral defects. Several systems are available for performing this procedure: the Mosaicplasty System (Smith and Nephew), the Osteochondral Autograft Transfer System (OATS; Arthrex), and the COR and COR2 systems (DePuy Mitek). Although mosaicplasty and OATS 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 six 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 OATS may be performed with either an open approach or arthroscopically. Osteochondral autografting has also been investigated as a treatment of unstable osteochondritis dissecans lesions using multiple dowel grafts to secure the fragment. While osteochondral autografting is primarily performed on the femoral condyles of the knee, osteochondral grafts have been used to repair chondral defects of the patella, tibia, and ankle. With osteochondral autografting, the harvesting and transplantation can be performed during the same surgical procedure. Technical limitations of osteochondral autografting are difficulty in restoring concave or convex articular surfaces, incongruity of articular surfaces that can alter joint contact pressures, short-term fixation strength and load-bearing capacity, donor-site morbidity, and lack of peripheral integration with peripheral chondrocyte death.

Filling defects with minced articular cartilage (autologous or allogeneic) is another single-stage procedure being investigated for cartilage repair. The Cartilage Autograft Implantation System (CAIS; Johnson and Johnson) harvests cartilage and disperses chondrocytes on a scaffold in a single-stage treatment. BioCartilage® (Arthrex) consists of a micronized allogeneic cartilage matrix that is intended to provide a scaffold for microfracture. DeNovo NT Graft (Natural Tissue Graft) is produced by ISTO Technologies with exclusive distribution rights by Zimmer. DeNovo NT consists of manually minced cartilage tissue pieces obtained from juvenile allograft donor joints. The tissue fragments are mixed intraoperatively with fibrin glue before implantation in the prepared lesion. It is thought that mincing the tissue helps both with cell migration from the extracellular matrix and with fixation.

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

DeNovo ET graft (ISTO Technologies) uses juvenile allogeneic cartilage cells.

Autologous chondrocyte implantation (ACI) is another method of cartilage repair involving the harvesting of normal chondrocytes from normal non-weight-bearing articular surfaces, which are then cultured and expanded in vitro and implanted back into the chondral defect. ACI techniques are discussed in the Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions Protocol.

Regulatory Status

The U.S. Food and Drug Administration (FDA) considers orthopedic manual surgical instruments as class I devices. If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and FDA clearance were not required before marketing the device in the United States. Harvesting and implantation are surgical procedures and therefore not subject to regulation by FDA.

Because there is no use of chemicals and minimal manipulation, allograft tissue does not require approval for marketing. 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 (CFR) title 21, parts 1270 and 1271.

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

Related Protocols

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Meniscal Allografts and Other Meniscal Implants

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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