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.
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.

<table>
<thead>
<tr>
<th>Site of Service for Elective Surgical Procedures</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medically necessary sites of service:</strong></td>
<td>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.</td>
</tr>
<tr>
<td>• Off campus-outpatient hospital/medical center</td>
<td></td>
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<tr>
<td>• On campus-outpatient hospital/medical center</td>
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<tr>
<td>• Ambulatory Surgical Center</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Inpatient hospital/medical center</th>
<th>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 patient 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):</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Anesthesia Risk</td>
<td>• ASA classification III or higher (see definition)</td>
</tr>
<tr>
<td></td>
<td>• Personal history of complication of anesthesia</td>
</tr>
<tr>
<td></td>
<td>• Documentation of alcohol dependence or history of cocaine use</td>
</tr>
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<td></td>
<td>• Prolonged surgery (&gt;3 hours)</td>
</tr>
<tr>
<td>• Cardiovascular Risk</td>
<td>• Uncompensated chronic heart failure (NYHA class III or IV)</td>
</tr>
<tr>
<td></td>
<td>• Recent history of myocardial infarction (MI) (&lt;3 months)</td>
</tr>
<tr>
<td></td>
<td>• Poorly controlled, resistant hypertension*</td>
</tr>
<tr>
<td></td>
<td>• Recent history of cerebrovascular accident (&lt; 3 months)</td>
</tr>
</tbody>
</table>
### Site of Service for Elective Surgical Procedures

<table>
<thead>
<tr>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Increased risk for cardiac ischemia (drug eluting stent placed &lt; 1 year or angioplasty &lt; 90 days)</td>
</tr>
<tr>
<td>- Symptomatic cardiac arrhythmia despite medication</td>
</tr>
<tr>
<td>- Significant valvular heart disease</td>
</tr>
<tr>
<td><strong>Liver Risk</strong></td>
</tr>
<tr>
<td>- Advance liver disease (MELD Score &gt; 8)**</td>
</tr>
<tr>
<td><strong>Pulmonary Risk</strong></td>
</tr>
<tr>
<td>- Chronic obstructive pulmonary disease (COPD) (FEV1 &lt; 50%)</td>
</tr>
<tr>
<td>- Poorly controlled asthma (FEV1 &lt; 80% despite treatment)</td>
</tr>
<tr>
<td>- Moderate to severe obstructive sleep apnea (OSA)***</td>
</tr>
<tr>
<td><strong>Renal Risk</strong></td>
</tr>
<tr>
<td>- End stage renal disease (on dialysis)</td>
</tr>
<tr>
<td><strong>Other</strong></td>
</tr>
<tr>
<td>- Morbid obesity (BMI ≥ 50)</td>
</tr>
<tr>
<td>- Pregnancy</td>
</tr>
<tr>
<td>- Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria])</td>
</tr>
<tr>
<td>- Anticipated need for transfusion(s)</td>
</tr>
</tbody>
</table>

* 3 or more drugs to control blood pressure


*** Moderate-AHI≥15 and ≤ 30, Severe-AHI ≥30

****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)

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<table>
<thead>
<tr>
<th>Inpatient hospital/medical center</th>
<th>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.</th>
</tr>
</thead>
</table>

### Treatment

<table>
<thead>
<tr>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteochondral fresh (human cadaver tissue) allografting may be considered medically necessary for treating chondral defects of the knee when ALL of the following criteria are met:</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Symptomatic focal full-thickness chondral defects of the knee are present</td>
</tr>
<tr>
<td></td>
<td>• Other cartilage repair techniques are inadequate due to lesion size, location, or depth such as:</td>
</tr>
<tr>
<td></td>
<td>o Microfracture</td>
</tr>
<tr>
<td></td>
<td>o Osteochondral autografting</td>
</tr>
<tr>
<td><strong>Osteochondral allografting</strong></td>
<td><strong>Osteochondral allografting may be considered medically necessary for treating the ankle when the following criteria are met:</strong></td>
</tr>
<tr>
<td></td>
<td>• Osteochondral lesions of the talus are large (area &gt;1.5 cm²) or cystic (volume &gt;3.0 cm³)</td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>•Autografting is inadequate due to lesion size, depth, or location.</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>• Revision surgery is needed for osteochondral lesions that are large (area &gt;1.5 cm²) or cystic (volume &gt;3.0 cm³):</td>
</tr>
<tr>
<td></td>
<td>o After failed prior marrow stimulation</td>
</tr>
<tr>
<td></td>
<td>o When autografting is inadequate due to lesion size, depth or location</td>
</tr>
<tr>
<td></td>
<td><strong>Osteochondral allografting for all other joints is considered investigational.</strong></td>
</tr>
</tbody>
</table>

- Adolescent patients should be skeletally mature with documented closure of growth plates (eg, 15 years or older)
- Adult patients that are considered an unsuitable candidate for total knee replacement (eg, younger than 55 years of age)
- Presence of debilitating symptoms that significantly limit ambulation
- Failed conventional medical treatment (including physical therapy and/or bracing techniques) and/or prior surgical treatment
- Body mass-index (BMI) is 35 kg/m² or less
- Symptomatic focal full-thickness articular cartilage defect is
Treatment | Medical Necessity
--- | ---
 | present
 | • Focal, full-thickness (grade III or IV) unipolar lesions of the or on the weight-bearing surface of the femoral condyles, trochlea, or patella between 1.0 and 2.5 cm² in size
 | • Minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less, see table below)
 | • Normal knee alignment and stability or correctable varus or valgus deformities achieved concurrently at the time of the procedure

Osteochondral autografting may be considered medically necessary for treating the ankle when the following criteria are met:

- Osteochondral lesions of the talus are large (area >1.5 cm²) or cystic (volume >3.0 cm³)
- Revision surgery is needed for an osteochondral lesion of the talus after failed marrow stimulation

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

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of focal articular lesions</td>
<td>Treatment of focal articular cartilage lesions with any of the following is considered investigational:</td>
</tr>
<tr>
<td></td>
<td>• Autologous minced or particulated cartilage (eg, the Cartilage Autograft Implantation System (CAIS), the Reveille Cartilage Processor)</td>
</tr>
<tr>
<td></td>
<td>• Allogeneic minced or particulated cartilage (BioCartilage, DeNovo Natural Tissue (NT) Graft)</td>
</tr>
<tr>
<td></td>
<td>• Decellularized osteochondral allograft plugs (eg, Chondrofix®)</td>
</tr>
<tr>
<td></td>
<td>• Reduced osteochondral allograft discs (eg, ProChondrix®, Cartiform®)</td>
</tr>
</tbody>
</table>
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 (eg, 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 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 patient’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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>27415</td>
<td>Osteochondral allograft, knee, open</td>
</tr>
<tr>
<td>27416</td>
<td>Osteochondral autograft(s), knee, open (eg, mosaicplasty) (includes harvesting of autograft[s])</td>
</tr>
<tr>
<td>28446</td>
<td>Open osteochondral autograft, talus (includes obtaining graft[s])</td>
</tr>
<tr>
<td>29866</td>
<td>Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) (includes harvesting of the autograft[s])</td>
</tr>
<tr>
<td>29867</td>
<td>Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)</td>
</tr>
</tbody>
</table>

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).
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, eg, 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, eg, walking short distances (20–100 m). Comfortable only at rest.
- **Class IV** Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

### Outerbridge Classification

<table>
<thead>
<tr>
<th>Grade</th>
<th>Pathology</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal cartilage</td>
</tr>
<tr>
<td>I</td>
<td>Softening and swelling of articular cartilage</td>
</tr>
<tr>
<td>II</td>
<td>Fragmentation and fissuring of articular cartilage affecting an area of less than 0.5 inches</td>
</tr>
<tr>
<td>III</td>
<td>Fragmentation and fissuring of articular cartilage affecting an area of greater than 0.5 inches</td>
</tr>
<tr>
<td>IV</td>
<td>Cartilage erosion to bone</td>
</tr>
</tbody>
</table>
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.

Evidence Review

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 osteoarthritis 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 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: 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**

Efficacy of the microfracture technique for articular cartilage lesions of the knee was examined by Mithoefer et al (2009) in systematic review.³ Twenty-eight studies (total N=3122 patients) were selected; 6 studies were randomized controlled trials (RCTs). Microfracture was found to improve knee function in all studies during the first 24 months after the procedure, but the reports on durability were conflicting. A prospective longitudinal study of 110 patients by Solheim et al (2016) found that, at a mean of 12 years (range, 10-14 years) after microfracture, 45.5% of patients had poor outcomes, including 43 patients who required additional surgery.⁴ The size of the lesion has also been shown to have an effect on outcomes following marrow stimulation procedures.

**Abrasion**

Fibrocartilage is generally considered to be less durable and mechanically inferior to the original articular cartilage. Thus, various strategies for chondral resurfacing with hyaline cartilage have been investigated. Alternatively, treatments of very extensive and severe cartilage defects may resort to complete replacement of the articular surface either by osteochondral allotransplant or artificial knee replacement.

**Osteochondral Grafting**

Autologous or allogeneic grafts of osteochondral or chondral tissue have been proposed as treatment alternatives for patients who have clinically significant, symptomatic, focal defects of the articular cartilage. It is hypothesized that the implanted graft’s chondrocytes retain features of hyaline cartilage that is similar in composition and property to the original articulating surface of the joint. If true, the restoration of a hyaline cartilage surface might restore the integrity of the joint surface and promote long-term tissue repair, thereby improving function and delaying or preventing further deterioration.
Both fresh and cryopreserved allogeneic osteochondral grafts have been used with some success, although cryopreservation decreases the viability of cartilage cells, and fresh allografts may be difficult to obtain and create concerns regarding infectious diseases. As a result, autologous osteochondral grafts have been investigated as an option to increase the survival rate of the grafted cartilage and to eliminate the risk of disease transmission. Autologous grafts are limited by the small number of donor sites; thus, allografts are typically used for larger lesions. In an effort to extend the amount of the available donor tissue, investigators have used multiple, small osteochondral cores harvested from non-weight-bearing sites in the knee for treatment of full-thickness chondral defects. Several systems are available for performing this procedure: the Mosaicplasty System (Smith and Nephew), the OATS (Osteochondral Autograft Transfer System; Arthrex), and the COR and COR2 systems (DePuy Mitek). Although mosaicplasty and autologous osteochondral transplantation (AOT) may use different instrumentation, the underlying mode of repair is similar (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 débridement and preparation of recipient tunnels. Multiple individual osteochondral cores are harvested from the donor site, typically from a peripheral non-weight-bearing area of the femoral condyle. Donor plugs range from 6 to 10 mm in diameter. The grafts are press fit into the lesion in a mosaic-like fashion into the same-sized tunnels. The resultant surface consists of transplanted hyaline articular cartilage and fibrocartilage, which is thought to provide “grouting” between the individual autografts. Mosaicplasty or AOT may be performed with either an open approach or arthroscopically.

Osteochondral autografting has also been investigated as a treatment of unstable osteochondritis dissecans lesions using multiple dowel grafts to secure the fragment. While osteochondral autografting is primarily performed on the femoral condyles of the knee, osteochondral grafts have been used to repair chondral defects of the patella, tibia, and ankle. With osteochondral autografting, the harvesting and transplantation can be performed during the same surgical procedure. Technical limitations of osteochondral autografting are difficulty in restoring concave or convex articular surfaces, incongruity of articular surfaces that can alter joint contact pressures, short-term fixation strength and load-bearing capacity, donor-site morbidity, and lack of peripheral integration with peripheral chondrocyte death.

Reddy et al (2007) evaluated donor-site morbidity in 11 of 15 patients who had undergone graft harvest from the knee (mean, 2.9 plugs) for treatment of osteochondral lesions of the talus. At an average 47-month follow-up (range, 7-77 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 AOT.\textsuperscript{6}

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 & 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 and 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 AOT or mosaicplasty.

ProChondrix (AlloSource) and Cartiform (Arthrex) are wafer-thin allografts where the bony
portion of the allograft is reduced. The discs are laser etched or porated and contain hyaline
cartilage with chondrocytes, growth factors, and extracellular matrix proteins. ProChondrix is
available in dimensions from 7 to 20 mm and is stored fresh for a maximum of 28 days.
Cartiform is cut to the desired size and shape and is stored frozen for a maximum of 2 years. The
osteochondral discs are typically inserted after microfracture and secured in place with fibrin
glue and/or sutures.

Autologous chondrocyte implantation 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 in a separate medical policy
(see \textbf{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 (eg, microfracture, drilling), there is evidence that osteochondral autografting decreases failure rates and improves outcomes in patients with medium-size lesions (eg, 2-6 cm²) 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 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 when autografting would be inadequate due to lesion size, location, or depth who receive fresh 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 (eg, microfracture, osteochondral autografting, ACI [autologous chondrocyte implantation]) would be inadequate due to lesion size, location, or depth. The evidence is sufficient to determine that the technology results in a meaningful 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 cm² who receive an osteochondral autograft, the evidence includes observational studies and a systematic review 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 (AOT). Given the success of marrow stimulation procedures for smaller lesions (<1.5 cm²) and the increase in donor-site morbidity with graft harvest from the knee, current evidence does not support the use of AOT as a primary treatment for smaller articular cartilage lesions of the ankle. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have large (area >1.5 cm²) or cystic (volume >3.0 cm³) full-thickness articular cartilage lesions of the ankle who receive an osteochondral autograft, the evidence includes an RCT and 2 observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. An RCT in patients with large lesions found similar efficacy for AOT, marrow stimulation, and arthroplasty at 2-year follow-up. Longer term results were not reported. Because observational studies of marrow stimulation in the talus have generally reported worse outcomes and high failure rates for large lesions, there is a strong rationale for using autografts. However, there is limited evidence that osteochondral autografts lead to better outcomes than microfracture at longer follow-up. The strongest evidence is derived from an observational study that showed good improvement on the Foot and Ankle Outcome Score through at least 5-year follow-up using AOT in both larger (2 plugs) and smaller (1 plug) lesions. Additional study is needed to evaluate the durability of AOT in larger lesions. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The best evidence for revision AOT comes from a nonrandomized comparative study that found better outcomes with AOT than with repeat marrow stimulation. This finding is supported by case series that have indicated good-to-excellent results at mid-term and longer term follow-up with revision AOT. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary full-thickness articular cartilage lesions of the ankle less than 1.5 cm² 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 cm² and AOT is effective as a revision procedure, use of allograft for small primary cartilage lesions has not been reported. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have large (area >1.5 cm$^2$) or cystic (volume >3.0 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 an RCT, case series, and a systematic review of case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review found a significant failure rate with osteochondral allografts for talar lesions. Although there is a potential to delay or avoid arthrodesis or total ankle arthroplasty in younger patients, use of an allograft may be detrimental to future treatments. Additional study is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

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. The RCT found that outcomes were slightly, but not significantly, worse with osteochondral allografts than with autografts. However, failure due to nonunion was higher in the allograft group, consistent with other reports. The evidence is insufficient to determine the effects of the technology on health outcomes.

**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. The literature on osteochondral autografts for advanced osteochondritis dissecans 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 with 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.

**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 the effects of the technology on health outcomes.

**Knee, Ankle, Elbow, or Shoulder Lesions Minced or Particulated Articular Cartilage**

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 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 small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The case series on decellularized osteochondral allograft plugs reported delamination of the implants, and high failure rates. Evidence on reduced osteochondral allograft discs consists only of case reports or very small case series. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01347892⁹</td>
<td>Post Market, Longitudinal Data Collection Study of Articular Cartilage Lesions in the Ankle Treated With DeNovo(R) NT</td>
<td>205</td>
<td>Sep 2019</td>
</tr>
<tr>
<td>NCT01329445⁹</td>
<td>Post Market, Longitudinal Data Collection Study of DeNovo NT for Articular Cartilage Defects of the Knee</td>
<td>160</td>
<td>Dec 2021</td>
</tr>
<tr>
<td>NCT01670617⁹</td>
<td>A Stratified, Post-Market Study of DeNovo NT for the Treatment of Femoral and Patellar Articular Cartilage Lesions of the Knee</td>
<td>90</td>
<td>Dec 2021</td>
</tr>
</tbody>
</table>

NCT: national clinical trial
⁹ Denotes industry-sponsored or cosponsored trial

Clinical Input Received 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 3 respondents, including 2 specialty society-level response and 1 physician from 1 health systems, while this policy was under review in 2017.

Based on the evidence and independent clinical input, the clinical input supports that the following indications provide a clinically meaningful improvement in the net health outcome and are consistent with generally accepted medical practice:

- Use of osteochondral autograft for:
Primary treatment of large (area >1.5 cm²) or cystic (volume >3.0 cm³) 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 cm²) or cystic (volume >3.0 cm³) 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.

Based on the evidence and independent clinical input, 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.

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

American Academy of Orthopaedic Surgeons

In 2010 guidelines, which remain available on the American Academy of Orthopaedic Surgeons website in 2018, on the diagnosis and treatment of osteochondritis dissecans, the Academy 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.48,49

A 2010 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.”50

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence conducted a 2005 review of mosaicplasty for knee cartilage defects. The corresponding guidance, released in 2006, stated that “There is some evidence of short-term efficacy, but data on long-term efficacy are inadequate.”51

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Regulatory Status**

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 FDA approved ISTO’s investigational new drug application for Neocartilage in 2006, which allowed ISTO to pursue phase 3 clinical trials of the product in human subjects. However, ISTO’s clinical trial for Neocartilage was terminated due to poor enrollment as of August 31, 2017.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/18</td>
<td>Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; references 21, 38, and 47 added; some references removed. “Or particulated” added to the investigational policy statements on minced cartilage. Other minor editing to policy statements for clarity only. Added CPT code 29867.</td>
</tr>
<tr>
<td>07/17/18</td>
<td>Minor edits for clarification.</td>
</tr>
<tr>
<td>09/21/18</td>
<td>Minor update, added Consideration of Age section.</td>
</tr>
<tr>
<td>04/01/19</td>
<td>Minor update, added Documentation Requirements section.</td>
</tr>
<tr>
<td>05/01/19</td>
<td>Minor update, clarified Site of Service requirements.</td>
</tr>
</tbody>
</table>

**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). ©2019 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.
Discrimination Is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5952. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):

يجوي هذا الإشعار معلومات هامة. قد يحتوي هذا الإشعار معلومات مهمة بخصوص طلبك أو طلبك. لا تزال هناك تأجيل زمنية في هذا الإشعار. قد تتاح إشعار آخر في تواريخ محددة للحصول على المعلومات المطلوبة أو المعلومات الأخرى. يمكن فتح الكتابة. يمكن أن تكون هذه المعلومات محدودة إلى كل محتوى أو طلبك. الطلب هو

800-722-1471 (TTY: 800-842-5357)

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):


Français (French):


Kreyòl ayisyen (Creole):


Deutsche (German):


Hmoob (Hmong):

Tsab ntawv tshaj xo no muaj cov ntsib ai luseem ceeb. Tej zaum tsab ntawv tshaj xo no muaj cov ntsib luseem ceeb tsox koy dain naaw thov kev pab los yoy koj kev kev pab cuam los ntawm Premera Blue Cross. Tej zaum muaj cov hnuv tseem ceeb cuam sau rau hauv dainm ntawm no. Tej zaum yoy koj yuav tau uaa qeem yam peb kom koy uaa tsip pub dhuav cov caj nyong uaa teev tseg rau hauv dainm ntawv no mas koy yuav yuav tau basis kev pab cuam koy hauv los yoy kev pab teum tej qiy koh moob ntawm. Koy muaj cai kom lawv muab cov ntsib luseem no uas tau muab sau uaa koy hom lus pub dawb rau koy. Hu rau 800-722-1471 (TTY: 800-842-5357).

Ilokio (Ilocano):

Daytoy a pakdaar mabalbin nga adda ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaa marbilin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonwo yonno coverage babaen iti Premera Blue Cross. Daytoy ket mobilin dagiti importante a pelsa iti daytoy a pakdaa. Mabalbin nga adda rumbeng nga aramidesto nga adda bakyab dagiti partikular a naatiding nga aldaw tapno mapagatalanneyo ti coverage ti salun-atyo yowo tengdagat gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tuling iti bukodoxy a pagasao nga awan ti bayadanyon. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

Premera Blue Cross: 800-842-5357 (TTY: 800-722-1471)

Polskie (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir dados importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):

Russian (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховах покрытии через Premera Blue Cross. В настоящем уведомлении могут быть ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llámenos al 800-722-1471 (TTY: 800-842-5357).

Тагалог (Tagalog):

ไทย (Thai):
ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญเกี่ยวกับการรักษาสุขภาพของคุณ Premera Blue Cross และคุณมีสิทธิ์ในการรับข้อมูลที่คุณควรรู้ ต่างจากการดำเนินการตามที่ระบุไว้ในประกาศนี้จะทำให้คุณมีสิทธิ์ในการรักษาสุขภาพของคุณได้ โปรดสื่อสารกับ Premera Blue Cross ที่ 800-722-1471 (TTY: 800-842-5357).

Українська (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані в цьому повідомленні. Існує можливість того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Зв'яжіться з номером телефону 800-722-1471 (TTY: 800-842-5357).