Introduction

A focal articular cartilage lesion is an area of damage to cartilage and possibly the bone beneath it. 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. 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 severely damaged cartilage 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 taken from a donor or the patient 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.
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

<table>
<thead>
<tr>
<th>Medically necessary sites of service:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Off campus-outpatient hospital/medical center</td>
</tr>
<tr>
<td>• On campus-outpatient hospital/medical center</td>
</tr>
<tr>
<td>• Ambulatory Surgical Center</td>
</tr>
</tbody>
</table>

**Medical Necessity**

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

**Medical Necessity**

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):

- **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)
  - 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)
## Site of Service for Elective Surgical Procedures

### Medical Necessity

- **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 criteria])**
  - **Anticipated need for transfusion(s)**

* 3 or more drugs to control blood pressure


*** 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**

Osteochondral fresh (human cadaver tissue) allografting may be considered medically necessary for treating cartilage defects of the knee when **ALL** of the following criteria are met:

- **Symptomatic focal full-thickness articular cartilage defect is present**
### Treatment | Medical Necessity
---|---
- Other cartilage repair techniques are inadequate due to lesion size, location, or depth:
  - Microfracture
  - Osteochondral autografting
  - Autologous chondrocyte implantation (see medical policy 7.01.48 Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions)

**Osteochondral allografting 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)

**AND**
- Autografting is inadequate due to lesion size, depth, or location.

**OR**
- Revision surgery is needed for osteochondral lesions that are large (area >1.5 cm²) or cystic (volume >3.0 cm³):
  - After failed prior marrow stimulation
  - When autografting is inadequate due to lesion size, depth or location

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

| Osteochondral autografting | Osteochondral autografting, may be considered medically necessary for treating cartilage defects of the knee when ALL of the following criteria are met:
---|---
- Adolescent patients should be skeletally mature with documented closure of growth plates (eg, 15 years or older)
- Adult patients 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
### Treatment

<table>
<thead>
<tr>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Body mass-index (BMI) is 35 kg/m² or less</td>
</tr>
<tr>
<td>• Symptomatic focal full-thickness articular cartilage defect is present</td>
</tr>
<tr>
<td>• Focal, full-thickness (grade III or IV) unipolar lesions of the patella or on the weight-bearing surface of the femoral condyles, trochlea, at least 1.0 to 2.5 cm² in size</td>
</tr>
<tr>
<td>• Minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less, see table below)</td>
</tr>
<tr>
<td>• Normal knee alignment and stability or correctable varus or valgus deformities achieved concurrently at the time of the procedure</td>
</tr>
</tbody>
</table>

**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.**

### Treatment

<table>
<thead>
<tr>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment of focal articular cartilage lesions with any of the following is considered investigational:</strong></td>
</tr>
<tr>
<td>• Autologous minced cartilage</td>
</tr>
<tr>
<td>• Allogeneic minced cartilage</td>
</tr>
<tr>
<td>• Decellularized osteochondral allograft plugs (eg, Chondrofix®)</td>
</tr>
<tr>
<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.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
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<tr>
<td>CPT</td>
<td></td>
</tr>
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<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>
</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).

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, 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>

Evidence Review

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, 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. Talar lesions are reported to be about 4% of osteochondral lesions. 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.

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. Procedures intended primarily to achieve symptomatic relief include débridement (removal of debris and diseased cartilage) and rehabilitation. Procedures intended to restore the articular surface may be targeted at the focal cartilage lesion, and most such treatments induce local bleeding, fibrin clot formation, and resultant fibrocartilage growth. These marrow stimulation procedures include abrasion arthroplasty, microfracture, and drilling, all of which are considered standard therapies.
**Microfracture**

Efficacy of the microfracture technique for articular cartilage lesions of the knee was examined in a 2009 systematic review.² 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.³ 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**

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 include 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). 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.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 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 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 Related Policies).

Summary of Evidence

Knee Lesions

For individuals who have full-thickness articular cartilage lesions of the knee who receive osteochondral autografts, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and longer term observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Several systematic reviews have evaluated osteochondral autografting for cartilage repair in the short and mid term. Compared to abrasion techniques (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 to fibrocartilage from abrasion techniques. There appears to be a relatively narrow range of lesion size for which osteochondral autografting is most effective. The best results have also been observed with lesions on the femoral condyles, although treatment of lesions on the trochlea and patella may also improve outcomes. Correction of malalignment is important for success of the procedure. The evidence suggests that osteochondral autografts may be considered an option for moderate-sized symptomatic full-thickness chondral lesions of the femoral condyle, trochlea, or patella. The
evidence is sufficient to determine that the technology results in 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 (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 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 cm$^2$ 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 or autologous osteochondral transplantation (AOT). Given the success of marrow stimulation procedures for smaller lesions (<1.5 cm$^2$) and the increase in donor-site morbidity with graft harvest from the knee, current evidence does not support the use of AOT as a primary treatment for smaller articular cartilage lesions of the ankle. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have large (area >1.5 cm$^2$) or cystic (volume >3.0 cm$^3$) 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 1 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 midterm 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 cm²) or cystic (volume >3.0 cm³) cartilage lesions of the ankle when autografting would be inadequate who receive a fresh osteochondral allograft, the evidence includes a small number of patients in an RCT, 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 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.

**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.

**Minced Articular Cartilage, Allograft Plugs and Discs for Knee, Ankle, Elbow, or Shoulder Lesions**

For individuals who have full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder who receive autologous or allogeneic minced articular cartilage, the evidence includes a small RCT and small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on autologous minced cartilage includes 1 small RCT 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 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 single 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>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td></td>
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<tr>
<td>NCT01347892</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>
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<td>NCT01329445</td>
<td>Post Market, Longitudinal Data Collection Study of DeNovo NT for Articular Cartilage Defects of the Knee</td>
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<td>Dec 2019</td>
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<tr>
<td>NCT01670617</td>
<td>A Stratified, Post-Market Study of DeNovo NT for the Treatment of Femoral and Patellar Articular Cartilage Lesions of the Knee</td>
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<td>Dec 2021</td>
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<tr>
<td><strong>Unpublished</strong></td>
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<tr>
<td>NCT01410136</td>
<td>A Post Market Study to Evaluate the Chondrofix® Osteochondral Allograft Utilized for Treatment of Subjects With Cartilage Lesions in the Knee</td>
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<td>Terminated (enrollment)</td>
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</table>
Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

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

Practice Guidelines and Position Statements

**American Academy of Orthopaedic Surgeons**

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.”

**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.”

**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

According to the manufacturer, the device is considered a class I device by the U.S. Food and Drug Administration (FDA) and is exempt from 510(k) requirements. This classification does not require submission of clinical data regarding efficacy but only notification of the FDA prior to marketing.

The 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. 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.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/01/17</td>
<td>New policy, approved October 10, 2017, effective February 2, 2018. Add to Surgery section. This policy was previously archived under policy number 7.01.506, but it is being reinstated. This service may be considered medically necessary when certain criteria are met, considered investigational when not met. Policy outlines investigational indications.</td>
</tr>
<tr>
<td>01/12/18</td>
<td>Minor edit, added Outerbridge Classification table.</td>
</tr>
<tr>
<td>03/01/18</td>
<td>Interim Review, approved February 27, 2018. Note added that this policy has been revised. Added Surgery Site of Service criteria, which becomes effective June 1, 2018.</td>
</tr>
<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>
</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). ©2018 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 any other 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 425-918-5922, 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)

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).

Oromoo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsénan aplikasyon w lan oswa konseñan kouvèt a asirans lan atravé Premera Blue Cross. Kapab genyen dayti ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka kenbe kouvèt a asirans sante w la oswa pou yo ka ede w akèk def yonpo. Se dwa w pou resewa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaak ket naglaon iti Napateg nga Impomarsion. Daytoy a pakdaak gabalin nga adda ket naglaon iti napateg nga impomarsion maipanggep iti aplikasyonowy yowo coverage babaen iti Premera Blue Cross. Daytoy ket gabalin dagiti importante a petaa iti daytoy a pakdaak. Gabalin nga adda rumbeng nga aramidenyo nga addang sakkay dagiti partikular a naitungit nga aldaw tapno mapagtalaineyo ti coverage ti salun-ayno yowo tulon kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impomarsion ken tulon iti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

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。本通知內可能有重要日期。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)。

037338 (07-2016)
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 claras 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. Llame al 800-722-1471 (TTY: 800-842-5357).

TAGALOG (Tagalog):

THAI (Thai):
ประกาศนี้อาจมีข้อมูลที่สําคัญเกี่ยวกับการการสมัครหรือขอบเขตประกันสุขภาพของคุณ Premera Blue Cross และจะมีข้อมูลในภาษารูปถึงคุณโดยตรงการส่งข้อมูลที่อันตรายและอาจมีกําหนดการในประกาศนี้ที่มีการใช้สัญญาที่ไม่ได้รับความยินยอมและข้อมูลส่วนบุคคลที่ไม่ได้รับการจัดเก็บ โปรดติดต่อที่ 800-722-1471 (TTY: 800-842-5357)

اللغة العربية (Arabic):
إذا تم إرسال معلومات عن طلب الرعاية الصحية، قد تكون هناك معلومات مهمة متعلقة بطلب الرعاية الصحية أو الحدود الاستثمارية لطلب الرعاية الصحية. الأرقام هم 800-722-1471 (TTY: 800-842-5357).