FEP 7.01.78 Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Effective Date: October 15, 2017

Related Policies:
- 7.01.15 Meniscal Allografts and Other Meniscal Implants
- 7.01.48 Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

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.

FDA 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 FDA prior to 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. 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. 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.

POLICY STATEMENT
Osteochondral fresh 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 (eg, microfracture, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to lesion size, location, or depth.
- Large (area >1.5 cm²) or cystic (volume >3.0 cm³) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location.
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- Revision surgery after failed prior marrow stimulation for large (area >1.5 cm²) or cystic (volume >3.0 cm³) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth or location.

Osteochondral allografting for all other joints is considered investigational.

Osteochondral autografting, 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). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., ≤55 years)
  - Focal, full-thickness (grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles, trochlea, or patella that are between 1 and 2.5 cm² 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.
- Large (area >1.5 cm²) or cystic (volume >3.0 cm³) osteochondral lesions of the talus.
- Revision surgery after failed marrow stimulation for osteochondral lesion of the talus.

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

Treatment 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, particularly for lesions less than 1.5 cm² in area or 3.0 cm³ in volume.

Severe obesity (e.g., body mass index >35 kg/m²) 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.
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at the same time. In addition, meniscal allograft transplantation may be performed in combination, either concurrently or sequentially, with osteochondral allografting or osteochondral autografting.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**RATIONALE**

**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 (eg, microfracture, osteochondral autografting, autologous chondrocyte implantation) would be inadequate due to lesion size, location, or depth. The evidence is sufficient to determine that the technology results in 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 or 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 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 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 primary full-thickness articular cartilage lesions of the elbow who receive an osteochondral autograft, the evidence includes 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 metaanalysis 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.

**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.

SUPPLEMENTAL INFORMATION

**Practice Guidelines and Position Statements**

**American Academy of Orthopaedic Surgeons**
In 2010 guidelines, which remain available on the American Academy of Orthopaedic Surgeons (AAOS) website in 2017, on the diagnosis and treatment of osteochondritis dissecans (OCD), AAOS was unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature or mature patients with an unsalvageable OCD lesion.

A 2010 AAOS review of articular cartilage restoration methods stated that “osteoochondral autografting is generally used for smaller focal lesions of the femoral condyle no greater than 1.5 to 2 cm.”

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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.

REFERENCES


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