

## **Corporate Medical Policy**

### Osteochondral Grafting of Articular Lesions

#### **Description of Procedure or Service**

Osteochondral autograft transplant (OAT) and mosaicplasty involve the transplantation of small plugs of healthy bone and hyaline cartilage from other joint surfaces to a damaged articular surface of the knee. Patients usually present with persistent pain following conservative management and prior unsuccessful surgery for osteochondral lesions. Small holes are drilled through the lesion and the newly harvested plugs are inserted into the holes. The Osteochondral Autograft Transfer System (OATS) is generally used in the transplantation of just one plug, whereas mosaicplasty refers to the transplantation of multiple (smaller) plugs to repair larger defects. Surgical access is through an open incision or via arthroscopy.

Osteochondral allografting involves transplantation of a piece of articular cartilage and attached subchondral bone from a cadaver donor to a damaged region of the articular surface of a joint. The goal of this procedure is to provide viable chondrocytes and supporting bone that will be sufficient to maintain the cartilage matrix and thereby relieve pain and reduce further damage to the articular surface of the joint.

#### **Background**

Hyaline cartilage, the naturally occurring cartilage which covers the weight-bearing surfaces of bones in mobile joints, is very durable but has a low capacity for regeneration because of its avascular and relatively acellular composition. Osteochondral (OC) surfaces that are damaged by trauma or degenerative processes usually fill in with fibrocartilage, which is less suitable for absorbing stress than hyaline cartilage, making the joint susceptible to further damage and development of arthritis.

Nonsurgical treatments for damage to articular cartilage include weight reduction, physical therapy, braces and orthotics, intra-articular injection of hyaluronic acid derivatives, and nonsteroidal anti-inflammatory agents. Many surgical options are available, including cartilage debridement or repair, subchondral drilling, abrasion, spongialization, microfracture, implants, OC grafting, autologous chondrocyte implantation (ACI), and total joint replacement.

There is no standard approach to the treatment of hyaline cartilage defects in the knee. Results from these conventional methods can be suboptimal or short-lasting, except in individuals with very low activity demands. If defects progress to severe osteoarthritis, total knee replacement (TKR) may become necessary.

Articular cartilage is not an inert tissue; it can remodel and rebuild itself in a limited fashion. Many studies have shown the metabolically active nature of this tissue, which underlies many procedures aimed at repair of focal chondral injury. The unique physiology of this tissue and its ability to heal when damaged requires consideration of the multilayered organization of articular cartilage and the role of the subchondral bone in providing the cellular and humoral factors for healing. The depth of the

articular insult directly influences the rate and ability of hyaline cartilage to heal. Mesenchymal stem cells, humoral factors, and the fibrin clot needed for preparing a milieu to promote repair are found in deeper in the subchondral bone. Developments in the understanding of the pathophysiology of articular cartilage and subchondral bone has given more scientific focus for management.

In a review of treatment of osteochondral injuries of the knee, Cain and Clancy (2001) stated that the treatment of osteochondral fractures and osteochondral lesions in the knee is controversial. Although results of many reconstructive procedures (e.g., autologous osteochondral mosaicplasty and osteochondral allograft transplantation) are quite encouraging with early follow-up, the ultimate goal is to prevent long-term degenerative arthritis. Continued studies are necessary to assess the effectiveness of these procedures in reaching the ultimate goal.

A recent systemic review assessed relevant literature for high quality randomized trials to assess the most appropriate treatments for knee cartilage defects. Eight studies compared microfracture to other treatment; four to autologous chondrocyte implantation (ACI) or matrix-induced ACI (MACI); three to osteochondral autologous transplantation (OAT); and one to BST-Cargel. Two studies reported better results with OAT than with microfracture and one reported similar results. Two studies reported superior results with cartilage regenerative techniques than compared with microfracture, and two reported similar results. At 10 years significantly more failures occurred with microfracture compared to OAT and with OAT compared to ACI. Larger lesions (>4.5 cm<sup>2</sup>) treated with cartilage regenerative techniques (ACI/MACI) had better outcomes than with microfracture. The authors concluded that no single treatment could be recommended for the treatment of knee cartilage defects. (Devitt, et al 2017)

Osteochondral transplants, in comparison with some of the other technical procedures available, demonstrate some advantages and few reported drawbacks. The goal is to resurface defects with hyaline cartilage in a one-step procedure. This procedure offers this opportunity without the need for support labs or additional costs. Yet, true double-blind comparisons with a sufficient number of patients and lengthy follow-up time are challenging. Given the rapid changes in technologies and techniques, the interest in repair of these defects must be tempered by the lack of true understanding of impact on health outcomes. With the available reports, it does appear that osteochondral grafting can be an efficacious procedure to restore traumatically damaged surfaces. Controversy persists as the exact role and scope of osteochondral grafting in the care of these patients continues to evolve.

### **Regulatory Status**

Transplantation of osteochondral (OC) autografts is a surgical procedure and, as such, is not subject to regulation by the FDA. However, the FDA does regulate manufacturing practice requirements applicable to drugs and devices. At least 2 kits, the Mosaicplasty® System and the Acufex® Mosaicplasty™ Comprehensive System (Smith & Nephew Endoscopy), have been reviewed and approved by the Center for Devices and Radiological Health.

## **Benefit Application**

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits.

**Related policy with specific coverage: refer to Autologous Chondrocyte Transplantation. policy**

## **Policy Statement**

GEHA will provide coverage for osteochondral grafting when it is determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated.

### **When treatment for Osteochondral Grafting is covered:**

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

Osteochondral allografting is proven medically necessary when **all** of the following criteria are met:

1. Adult who has achieved mature skeletal growth with documented closure of growth plates
2. Symptomatic focal full-thickness articular cartilage defect
3. Considered unsuitable candidate for total knee replacement
4. Presence of debilitating symptoms that significantly limit ambulation
5. Normal alignment or correctable varus or valgus deformities
6. Minimal to absent degenerative changes in surrounding articular cartilage (Outerbridge Grade II or less)
7. Failed conventional medical treatment (including physical therapy and/or bracing techniques) and/or prior surgical treatment

B. Osteochondral autografts (OATS or mosaicplasty) may be considered medically necessary for symptomatic focal full-thickness articular cartilage defects of the knee when **all** of the following criteria are met:

1. The member is skeletally mature with documented closure of growth plates *and* is not considered a candidate for total knee replacement (i.e., members under 15 years or over 55 years of age); ***and***
2. The member has disabling symptoms limiting ambulation that have not been relieved by appropriate non-surgical therapies (e.g., medication, physical therapy); ***and***
3. The member has focal, full thickness (grade III or IV) unipolar lesions on the weight bearing surface of the femoral condyles or trochlea; ***and***

4. The member has 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; **and**
5. The member has normal alignment or correctable varus or valgus deformities.

### **When Osteochondral Grafting is not covered**

Osteochondral grafting is considered experimental and thus, not covered, for the following indications or scenarios, including but not limited to:

- A. Osteochondral autografts (OATS, mosaicplasty) of all other joints (ankle, elbow, hip, patella, shoulder);
- B. Treatment of focal articular cartilage lesions with autologous minced cartilage
- C. Treatment of focal articular cartilage lesions with allogeneic minced cartilage
- D. Treatment of focal articular cartilage lesions with decellularized osteochondral allograft plugs (eg, Chondrofix)
- E. Treatment of focal articular cartilage lesions with reduced osteochondral allograft discs (eg, ProChondrix, Cartiform)
- F. Hybrid autologous chondrocyte implantation performed with osteochondral autograft transfer system (Hybrid ACI/OATS) technique for the treatment of osteochondral defects
- G. Use of non-autologous mosaicplasty using resorbable synthetic bone filler materials (including but not limited to plugs and granules) to repair osteochondral defects of the ankle or knee
- H. Use of synthetic resorbable polymers (e.g., PolyGraft BGS, TruFit [cylindrical plug], TruGraft [granules])

### **Policy Guidelines**

Osteochondral grafting may be performed via open approach or via arthroscopy depending on the characteristics of the anatomy involved and/or the experience and preference of the attending surgeon.

### **Physician documentation**

Completed GEHA Osteochondral Procedure form (This can be found on the [geha.com](http://geha.com) website).

Results of Arthroscopic assessment or MRI

History and Physical performed with the last 12 months

Documentation of conservative treatment and results of conservative treatment

Any other such documentation to provide evidence that member meets the coverage criteria set forth in this policy.

Applicable Codes include but are not limited to:

27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft[s])
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)

### **Scientific references**

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### **Policy implementation and updates**

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May 2019 Formatting updates. No policy coverage changes. Updated references

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