

# MEDICAL POLICY



<b>SUBJECT: OSTEOCHONDRAL GRAFTING</b>	<b>EFFECTIVE DATE: 12/19/02</b>
<b>POLICY NUMBER: 7.01.59</b>	<b>REVISED DATE: 07/15/04, 08/18/05, 07/20/06, 06/21/07, 05/14/08, 04/16/09, 03/18/10, 03/17/11, 02/16/12, 02/21/13, 02/20/14</b>
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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

## POLICY STATEMENT:

- I. Based upon our criteria and assessment of the peer reviewed medical literature, osteochondral autografting and allografting using one or more cores of osteochondral tissue, are **medically appropriate** for treatment of cartilaginous defects caused by acute or repetitive trauma in the knee or ankle when all of the following criteria are met.
- A. Patient age is 15-50 years;
  - B. Cartilage defect size is equal to or greater than 1cm<sup>2</sup>;
  - C. The defect is a focal, full thickness isolated defect of the weight bearing surface of the talus or the medial or lateral femoral condyles or trochlear region of the knee;
  - D. The defect is unipolar;
  - E. The lesion is largely contained with near normal surrounding articular cartilage and articulating cartilage (grades 0,1, 2);
  - F. In the knee the meniscus is intact or has stable partial tears. Partial meniscectomy may be indicated and does not preclude osteochondral grafting;
  - G. A normal or near normal joint space (no more than 15% joint space narrowing) is present;
  - H. There is no active infection;
  - I. There is no inflammation or osteoarthritis in the joint;
  - J. The patient has disabling, localized knee or ankle pain of at least 6 months duration that has failed to respond to conservative treatment and has failed abrasion arthroplasty and/or microfracture techniques;
  - K. The joint is stable with normal alignment. A procedure to correct alignment may be performed in combination with or prior to grafting;
  - L. The patient is willing and able to comply with post-operative weight-bearing restrictions and rehabilitation; and
  - M. There is no history of cancer in the bones, cartilage, fat or muscle of the affected limb.
- II. Based upon our criteria and assessment of the peer-reviewed literature, osteochondral grafting has not been medically proven to be effective and is **investigational** for use in joints other than the knee and ankle.

*Refer to Corporate Medical Policy #7.01.38 regarding Autologous Chondrocyte Implantation.*

## POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

## DESCRIPTION:

Osteochondral auto-and allografting have been investigated for full-thickness cartilage defects of weight bearing surfaces due either to trauma or conditions such as osteochondritis dissecans. Overall, the goal of osteochondral grafting procedures is to re-establish the cartilage matrix with chondrocytes and supporting bone in order to improve joint function and decrease pain. The procedure entails one or more small grafts of bone and cartilage being harvested from either the patient's non-weight bearing surfaces/surfaces that bear less weight (autograft) or from a cadaver joint (fresh or cryopreserved allograft). The base of the defect is then abraded or curetted down to subchondral bone, and the grafts are

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implanted in the defect. Use of autografting is associated with repairing smaller defects, whereas, allografts are utilized for larger defects. The advantages of using autograft material include graft availability, the absence of possible disease transmission risk, and that the procedure is a single-stage procedure. Disadvantages include donor site morbidity and limited available graft volume. In addition, tissue may have to be harvested from two different donor sites in order to provide enough material for a large defect without compromising the donor site. The use of allograft cartilage has the advantage of providing osteochondral segments that are able to survive transplant, having the ability to heal to recipient-site tissue, and no associated donor site morbidity. Application of osteochondral allografting is limited because cryopreserved allografts do not contain an acceptable level of cartilage viability, and cryopreservation may decrease the viability of the cartilage cells. Fresh osteochondral allografts must be implanted within 72 hours of donor death, may be difficult to obtain (due to scarcity) and may also entail a concern of disease transmission. A well-organized transplant program is required, and the surgery cannot be done on an elective basis.

Recently, a minimally processed osteochondral allograft (Chondrofix®, Zimmer) has become available for use. 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 OATS or mosaicplasty.

Several systems are available for performing this procedure: the Mosaicplasty System (Smith and Nephew), the Osteochondral Autograft Transfer System (OATS, Arthrex, Inc.), and the COR and COR2 systems (DePuy-Mitek). The OATS procedure involves use of larger plugs usually filling the entire defect with a single plug while mosaicplasty uses multiple small cylindrical plugs. It is suggested that mosaicplasty reduces the possibility of donor site morbidity and produces a more congruent surface. In both of these techniques, harvesting and transplantation is performed during the same surgical procedure. The COR and COR2 systems can be utilized for autograft or allograft transplantation.

**RATIONALE:**

Osteochondral autografting and allografting are surgical procedures and do not require FDA approval.

While there are no published randomized controlled trials comparing outcomes of these procedures with conventional treatment, case series from a number of centers demonstrate relief of symptoms and improved function in a subset of patients who had failed conservative management and arthroscopic or other surgical treatments.

L Hangody, et al. (2008) reported on over 15 years of clinical experience with autologous osteochondral mosaicplasty. Over 1,000 mosaicplasty patients were assessed to confirm the survival of transplanted hyaline cartilage and fibrocartilage filling of donor sites located on relatively less weightbearing surfaces, as well as donor-site disturbances and morbidity. Analysis of clinical scores has shown good to excellent results in 92% of patients with femoral condylar implantations, 87% of tibial resurfacements, 74% of patellar and/or trochlear mosaicplasties and 93% of talar procedures. Long-term donor-site complaints measured by the Bandi score were minor and present only in 3% of patients. 81 out of the 98 control arthroscopies represented congruent and good gliding surfaces and histologically proven survival of the transplanted hyaline cartilage as well as fibrocartilage covering of the donor sites. Complications in the entire patient group were four deep infections and four deep venous thromboses. In nearly 8% of the cases excessive intraarticular bleeding was observed in the early postoperative period, as a minor complication of the procedure. Multicentric, comparative, prospective evaluation of 413 arthroscopic resurfacing procedures (mosaicplasty, Pridie drilling, abrasion arthroplasty and microfracture cases in homogenised subgroups) demonstrated that mosaicplasty resulted in favorable clinical outcome in the long-term follow-up compared to other three techniques. Durability of the early results was confirmed in long-term evaluations both of the femoral condylar implantations and talar mosaicplasties. The authors concluded that autologous osteochondral mosaicplasty may be an alternative for small and medium-sized focal chondral and osteochondral defects of weightbearing surfaces of the knee and other weight bearing synovial joints.

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**CODES:**     Number                    Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<b>CPT:</b>	27415	Osteochondral allograft, knee, open
	27416	Osteochondral autograft(s), knee, open (e.g. mosaicplasty) (includes harvesting of autograft[s])
	28446	Open osteochondral autograft, talus (includes obtaining graft[s])
	29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) ( includes harvesting of the autograft)
	29867	osteochondral allograft (eg, mosaicplasty)

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**HCPCS:**    No code

<b>ICD9:</b>	732.7	Osteochondritis dissecans
	717.7	Chondromalacia of patella
	719.86-.87	Other and unspecified disorders of joint, lower leg, ankle and foot

<b>ICD10:</b>	M22.40-M22.42	Chondromalacia patella, knee (code range)
	M23.8x1-M23.92	Other internal derangement of knee (code range)
	M93.261-M93.269	Osteochondritis dessicans knee (code range)
	M93.271-M93.279	Osteochondritis dessicans ankle and joint of foot (code range)
	M94.261-M94.269	Chondromalacia of knee (code range)
	M94.271-M94.279	Chondromalacia of ankle and joints of foot (code range)

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\* key article

**KEY WORDS:**

Chondral defects, Chondrofix®, COR, COR2, Mosaicplasty, OATS, Osteochondral autograft, Osteochondral allograft, Osteochondral autograft transfer procedure.

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## **CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

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Based on our review, osteochondral grafting is not addressed in National or Regional Medicare coverage determinations or policies.