IEHP UM Subcommittee Approved Authorization Guideline

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<th>Guideline</th>
<th>Treatment of Osteochondral Defects</th>
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**COVERAGE POLICY**

I. Autologous Chondrocyte Implants (ACI)

IEHP considers Autologous Chondrocyte Implants medically necessary for repairing cartilage defects of the knee in Members who have symptoms of disabling knee pain related to a full thickness, focal chondral defect with all of the following:

A. Age 15-60 years; and
B. BMI ≤ 35; and
C. Persistence of disabling pain and/or knee locking or at least 6 months with
   1. Failure of conservative therapy (minimum of 2 months of physical therapy)
   2. Failure of established surgical interventions (i.e., microfracture, drilling, abrasion)
      a. Diagnostic arthroscopy, lavage, or debridement is not considered adequate to meet this criterion; and
D. Focal articular full thickness (grade III or IV) cartilage defect on a load bearing surface of the femoral condyle (medial, lateral, or trochlear; not in the patellofemoral area) with near normal surrounding articular and articulating cartilage; and
E. Size of defect measures <7mm in depth, <6.0 cm in length, and area at least 2 square cm; and
F. Stable and normally aligned knee with intact meniscus and normal joint space on x-ray.
   1. A corrective procedure in combination with, or prior to, chondrocyte implantation may be necessary to ensure stability, alignment and normal weight distribution within the joint; and
G. No active infection, inflammation, or osteoarthritis present in the joint; and
H. No history of cancer of the bones, cartilage, fat or muscle of the affected limb; and
I. Member agrees to observe post-operative weight bearing restrictions and participate in rehabilitation

II. Osteochondral Autograft Transfer System (OATS)

IEHP considers the Osteochondral Autograft Transfer System (OATS) or Mosaicplasty medically necessary in Members who meet all of the following criteria:

A. The Member is skeletally mature with documented closure of growth plates (i.e., 15 years or older); and
B. The Member is not considered a candidate for total knee replacement (i.e., member is under 55 years of age); and
C. Persistence of disabling symptoms for at least 6 months that limits ambulation and has not been relieved by appropriate non-surgical therapies (e.g., medication, physical therapy); and
D. The Member has focal, full thickness (grade III or IV) unipolar lesions of the weight
bearing surface of the femoral condyles or trochlea as detailed by arthroscopic examination; and
E. Size of the cartilage defect is between 2-4 square cm in total area; and
F. 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
G. The Member has normal alignment or correctable vargus or valgus deformities

III. Osteochondral Allograft Transplant
IEHP considers Osteochondral Allograft Transplant to be medically necessary in Members who meet the following criteria:
A. Age 15-60 years; and
B. BMI ≤ 35; and
C. No active infection, inflammation, or osteoarthritis present in the joint; and
D. No history of cancer in the bones, cartilage, fat or muscle of the affected limb and
E. Member agrees to observe post-operative weight bearing restrictions and participate in rehabilitation
F. Non-repairable stage 3 and 4 osteochondritis dissecans; or
G. Otherwise healthy, active, Members who have either failed earlier arthroscopic procedures or are not candidates for such procedures because of the size, shape, or location of the lesion; or
H. Treatment of a focal lesion that meets the following criteria:
   1. Full-thickness depth (grade 3 and 4) lesion 4 square cm or more in diameter by MRI or arthroscopy; and
   2. Preferably surrounded by normal, healthy (non-arthritic) cartilage; and
   3. Causing disabling localized knee pain that is unresponsive to conservative treatment (e.g., medication, physical therapy); and
   4. Normal knee alignment or knee alignment will be surgically corrected (i.e., by osteotomy) at time of allograft; and
   5. The opposing articular surface should be generally free of disease or injury, including no arthritis on the corresponding tibial surface

COVERAGE LIMITATIONS AND EXCLUSIONS
IEHP considers Autologous Chondrocyte Implants for all other indications to be experimental and investigational including but not limited to patellar or talar lesions or lesions of other joints because the effectiveness of Autologous Chondrocyte Implants for these lesions has not been established.

ADDITIONAL INFORMATION
Articular cartilage lesions in the knee can occur through trauma or chronic repetitive overload such as in athletes. These lesions can cause substantial pain and disability. The defects often fail to heal spontaneously due to their avascularity and minimal chondrocyte migration and propagation. (Schrock, 2017) If left uncorrected, cartilage defects of the knee may increase the chance of osteoarthritis (Welch 2017, Devitt 2017)

Autologous Chondrocyte Implantation (ACI) aims to restore isolated cartilage lesions by inducing hyaline-like cartilage formation. This is opposed to mesenchymal stimulation (such as microfracture) that attempts to induce formation of fibrocartilage, which is less durable and
biomechanically inferior to hyaline cartilage. (Mistry, 2017)

Autologous chondrocyte implantation is a multiple step process. First, normal cartilage is harvested from a joint margin during an arthroscopic biopsy procedure. This specimen of live articular cartilage is placed into the culture medium and chondrocyte cells are separated from the cartilage. Chondrocytes undergo a culturing process before they are implanted into the cartilage defect in a second open arthrotomy procedure. This is followed by extensive rehabilitation.

**The Osteochondral Autograft Transfer System** (OATS) is a procedure wherein a cylindrical graft of healthy cartilage and subchondral bone is taken from an area of the knee that undergoes less stress and transferred to replace an articular cartilage defect in a higher stress area. (Richter 2016) If multiple small plugs are used to fill the defect, the procedure is called mosaicplasty. The underlying principle is that the transferred cartilage will grow to cover the edges of the core with hyaline cartilage cells and not the weaker fibrocartilage cells.

Some studies suggest that small lesions are best treated with either microfracture or OAT, while larger lesions (>4 sq cm) have shown better outcome with ACI (Richter 2016).

**Osteochondral Allograft Transplantation** is a technique to repair cartilage defects wherein cadaveric cartilage and subchondral bone is transferred to fill the lesion rather than a graft from the patient’s own cartilage and bone. Advantages of this technique include transplant of viable hyaline cartilage to the lesion, the ability to fill larger defect sizes (>4 square cm), and completion in one procedure versus two with ACI. (Zouzias, Richter 2015)

**REFERENCES**


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