IEHP UM Subcommittee Approved Authorization Guidelines
Osteochondral Autografts and Allografts

Policy:
A. IEHP considers Osteochondral Mosaicplasty experimental and investigational because its effectiveness in the treatment of articular cartilage defects/lesions has not been established.

B. IEHP considers Osteochondral Autograft Transfer System (OATS) experimental and investigational because its effectiveness in the treatment of articular cartilage defects/lesions has not been established.

C. IEHP considers Autologous Chondrocyte Implants medically necessary for repairing cartilage defects of the knee in Members who meet the following selection criteria:

Member has symptoms of disabling knee pain related to a full thickness, focal chondral defect with all of the following:

1. Age 15–45 years; and
2. Weight less than 150% of ideal using the Metropolitan Life Indices; and
3. Presence of disabling pain and/or knee locking; and
4. Focal articular cartilage defect down but not through the subchondral bone on a load bearing surface of the femoral condyle (medial, lateral, trochlear) (not in the patellofemoral area); and
5. Size of defect measures <7mm in depth, <6.0 cm in length, and area ranging from 1.6–10 square cm; and
6. Stable knee with intact meniscus and normal joint space on X-ray; and
7. No active inflammatory or other arthritis, clinically and by X-ray; and
8. Procedure is not being done for treatment of degenerative arthritis (osteoarthritis); and
9. Failure of conservative therapy (minimum of 2 months of physical therapy) as well as established surgical interventions (i.e., microfracture, drilling, abrasion) (diagnostic arthroscopy, lavage, or debridement is not considered adequate to meet this criterion); and
10. Cooperative person for post-operative weight bearing restrictions and activity restrictions together with a potential for completion of post-operative rehabilitation; and

11. Informed consent with realistic expectations.

IEHP considers Autologous Chondrocyte Implants experimental and investigational for patellar or talar lesions or lesions of other joints because the effectiveness of Autologous Chondrocyte Implants for these lesions has not been established.

1. Mosaicplasty is a relatively new, reconstructive bone grafting procedure for the treatment of articular defects of the knee, ankle, and hip. In general, treatment of articular defect of the knee by mosaicplasty entails transplantation of small cylindrical osteochondral grafts (4 to 10 mm in diameter, 15 to 20 mm deep) from the less weight-bearing periphery of the femoral condyles at the level of the patello-femoral joint, and transplanting them in a mosaic-like fashion into a prepared defect site on the weight-bearing surfaces of the same knee. Its goal is to produce a smooth gliding articular surface of hyaline or hyaline-like cartilage in weight-bearing surfaces of the knee. Mosaicplasty is carried out either by an open approach or arthroscopically if the defect/lesion is small and not more than 4 to 6 grafts are needed. Both open and arthroscopic mosaicplasty require a relatively short rehabilitation period – normal daily activity can be allowed after 5 to 8 weeks.

2. Osteochondral autograft transfer system is a procedure employed for medium sized areas of discrete damage (mosaicplasty is employed for even larger but discrete areas of damage). The OATS procedure focuses on chondral defects that are associated with chronic tears of the anterior cruciate ligament (ACL), using an arthroscopic approach that can provide access to both the ACL for reconstruction and performance of the autograft. The orthopedic surgeon uses an apple-corer like instrument to core out a circle of damaged cartilage and replaces it with a piece of normal cartilage from a less important part of the same knee. The underlying principal is that the transferred cartilage will grow to cover the edges of the core with proper cartilage cells and not the weaker fibrocartilage cells.

3. Autologous Chondrocyte Implants (autologous chondrocyte transplant) (Carticel, Genzyme Inc., Cambridge, MA) has been investigated as a means of a three-step treatment for repairing cartilage defects in the knee. First, normal cartilage is harvested from a joint margin during an arthroscopic biopsy procedure. This biopsy of an articular surface serves as the source of cultured chondrocytes. This specimen of live articular cartilage is placed into a culture medium. Under a strictly controlled environment the cells are separated from the cartilage. These cells are then multiplied using a cell-culture technique. They are stored in the frozen state and are thawed and have a final culturing process before they are shipped to the operating room on the day of the implantation. It takes about six weeks to culture chondrocytes for implantation. Approximately 12 million cartilage cells are present in the 0.4ml medium that is ultimately implanted into the defect. The cultured chondrocytes are implanted into the cartilage defect in a second open arthrotomy procedure.
Recently published controlled clinical trials have compared Autologous Chondrocyte Implant to established procedures. Although results of available clinical studies have not been consistent, the strongest available evidence suggests that outcomes of microfracture may be superior to Autologous Chondrocyte Implant. Knutsen, et al. (2004) compared short-term clinical outcomes of Autologous Chondrocyte Implantation and microfracture in a randomized controlled clinical trial involving 80 persons with a single symptomatic cartilage defect on the femoral condyle. At two-years follow-up, the investigators reported significantly better improvement in functional status (according to the SF-35 physical component score) in the microfracture group than in the Autologous Chondrocyte Implantation group.

A study reported in abstract form by Anderson et al. (2003) compared autologous chondrocyte implantation with microfracture in 45 patients with full-thickness cartilage lesions greater than 2 cm in size. The investigators reported a mean improvement in the Cincinnati score was 3.1 for Autologous Chondrocyte Implantation and 1.3 for microfracture. The investigators reported that the reduction in pain was also better with Autologous Chondrocyte Implantation compared with microfracture. Although this study was prospective, there was no random assignment to treatment groups; thus this study is of weaker design than the previously reported study by Knutsen, et al. (2004). In addition, this study has been criticized for having a high percentage of worker’s compensation patients, and 5 of the 23 patients treated with microfracture were lost to follow-up.

Two controlled clinical trials comparing Autologous Chondrocyte Implantation with osteochondral transplant procedures have been published in recent years, with inconsistent results. Bentley, et al (2003) reported on the results of a randomized controlled clinical trial comparing Autologous Chondrocyte Implantation to mosaicplasty in 100 patients with symptomatic defects of the articular cartilage of the knee. After a mean follow-up of 19 months, functional assessment using the modified Cincinnati and Stanmore scores and objective clinical assessment showed that 88% had excellent or good results after Autologous Chondrocyte Implantation compared with 69% after mosaicplasty. Horas, et al. (2003) reported on the results of a randomized clinical study comparing transplantation of an osteochondral cylinder to Autologous Chondrocyte Implantation in forty patients with an articular cartilage lesion of the femoral condyle. The investigators reported that the improvements in function in subjects receiving Autologous Chondrocyte Implantation lagged behind subjects receiving osteochondral cylinder transplantation. In addition, the investigators reported that the defects treated with Autologous Chondrocyte Implantation were primarily filled with fibrocartilage rather than hyaline cartilage. These studies have been criticized for the short duration of follow up. LaPrade (2003) commented that “further study with a minimum follow-up of 5 years as well as complete and thorough histologic analysis is needed to determine which technique, Autologous Chondrocyte Implantation or autogenous osteocartilageous transfer, is best.”

There are no adequate prospective clinical studies of the effectiveness of Autologous Chondrocyte Implantation on defects of the patella or talus. Prospective, randomized clinical studies are needed to assess the impact on functional status, disability, and pain. In addition, studies need to compare the effectiveness of Autologous Chondrocyte Implantation to established methods of treatment of patellar or talus defects.
Bibliography:

1. Milliman Care Guidelines, Ambulatory Care, 10th Edition
2. Aetna, Clinical Policy Bulletins, December 9, 2005


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