Clinical Coverage Guidelines: **Osteochondral Treatments for Defects of the Knee**

**Current Effective Date:** 11/01/12  
**Original Effective Date:** 11/01/08*  
**Policy Number:** OCA: 3.965  
**Product Applicability:**  
- MassHealth  
- Commonwealth Care  
- Commercial

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**Summary:** The Plan considers autologous chondrocyte transplantation (ACT), osteochondral autograft transplantation (OATS/mosaicplasty), and osteochondral allograft transplantation procedures medically necessary for osteochondral defects of the knee when specific criteria are met. Prior authorization is required. The use of autologous chondrocyte transplantation, osteochondral allograft transplantation, and osteochondral autograft transplantation (OATS/mosaicplasty) are considered experimental and investigational for all other joints.

**Description of Item or Service:**

**Autologous Chondrocyte Transplantation (ACT):** Also known as autologous chondrocyte implantation (ACI), ACT is a two-stage surgical procedure where the patient’s own chondrocytes or cartilage cells are removed and grown in a lab to generate more cells. The cultured cells are then re-implanted into the knee at areas where there are cartilage defects with the goal of regenerating cartilage over the next 6-12 months to improve joint function and pain. (Carticel®, autologous cultured chondrocytes, is an FDA approved ACT cell-based replacement technology developed by Genzyme Corp.)

**Osteochondral Allograft Transplantation:** A surgical procedure where bone and cartilage plugs are taken from a cadaver donor and transplanted into the patient’s knee joint to stimulate growth of articular cartilage on the surface of the knee joint.

**Osteochondral Autograft Transplantation (OATS) and Mosaicplasty:** Surgical procedures where bone and cartilage plugs are taken from low weight bearing surfaces of the patient’s joint and inserted into the affected area of the same patient to stimulate growth of articular cartilage on the surface of the knee joint. This procedure is a
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Note: The Plan member seeking osteochondral treatment of the knee should be a skeletally mature adult between 18 and 55 years of age. If an adolescent patient is evaluated, s/he should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). An adult patient should not be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery. The Plan members’ body mass index (BMI) is recommended to be less than or equal to 35 for improved surgical outcomes by decreasing stress from weight-bearing on the joint.

**Definition:**

**Microfracture Surgery:** Microfracture surgery is a surgical procedure that can help restore knee cartilage by creating tiny fractures in the adjacent bones, causing new cartilage to develop.

**Clinical Guideline Statement:**

The Plan considers autologous chondrocyte transplantation (ACT), osteochondral autograft transplantation (OATS/mosaicplasty), and osteochondral allograft transplantation procedures medically necessary for osteochondral defects of the knee when:

- The member has persistent symptoms of disabling localized knee pain for at least six (6) months; and
- The member has failed to respond to conservative treatment (e.g., physical therapy, braces, and/or non-steroidal anti-inflammatory drugs).

**ALL** of the following specific criteria must be met to obtain Plan prior authorization for each of the procedures specified below:

1. **Autologous Chondrocyte Transplantation (ACT)/Autologous Chondrocyte Implantation (ACI):**
   - Inadequate response to prior arthroscopic or other surgical repair (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft)
   - Condition involves a full thickness cartilaginous defect (Grade III-IV) of the femoral condyle (medial, lateral or trochlea) caused by acute or repetitive trauma; acute trauma may result from falls, sports, and other sources of impact while repetitive trauma may include overuse
   - Femoral condyle defect size of 1 to 12 cm squared in total area
   - No generalized tibial defect size of 1 to 12 cm squared in total area
• No known history of hypersensitivity to gentamicin, other aminoglycosides or materials of bovine origin
• No osteoarthritis of the knee
• Stable and aligned knee (corrective procedures may be performed in combination with or prior to ACT)
• Normal articular cartilage at lesion border
• Patient motivated and willing to comply with rigorous rehabilitation program
• No active infection
• No history of cancer in the bone, cartilage, fat or muscle of the treated limb

2. Osteochondral Allograft Transplantation:
• Cartilage defect size is ≥ 2cm squared in total area
• Condition involves a full thickness cartilaginous defect (Grade III-IV) of the femoral condyle (medial, lateral or trochlea) caused by acute or repetitive trauma; acute trauma may result from falls, sports, and other sources of impact while repetitive trauma may include overuse
• No osteoarthritis of the knee
• Knee is stable with intact, fully functional menisci and ligaments
• Normal knee alignment
• Normal joint space
• Patient motivated and willing to comply with rigorous rehabilitation program
• No active infection
• No history of cancer in the bone, cartilage, fat or muscle of the treated limb

3. Osteochondral Autograft Transplantation (OATS/mosaicplasty):
• Cartilage defect size is between 1.0-2.5cm squared in total area
• Condition involves a full thickness cartilaginous defect (Grade III-IV) of the femoral condyle (medial, lateral or trochlea) caused by acute or repetitive trauma; acute trauma may result from falls, sports, and other sources of impact while repetitive trauma may include overuse
• No osteoarthritis of the knee
• Knee is stable with intact, fully functional menisci and ligaments
• Normal knee alignment
• Normal joint space
• Patient motivated and willing to comply with rigorous rehabilitation program
• No active infection
• No history of cancer in the bone, cartilage, fat or muscle of the treated limb

Autologous chondrocyte transplantation, osteochondral allograft transplantation, and osteochondral autograft transplantation (OATS/mosaicplasty) are considered experimental and investigational for use in all other joints.

**Applicable Coding:**
Applicable coding is listed below, subject to codes being active on the date of service. Because the American Medical Association (AMA), Centers for Medicare & Medicaid Services (CMS), and the U.S. Department of Health and Human Services may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes may not be all inclusive. These codes are not intended to be used for coverage determinations.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<tbody>
<tr>
<td>27412</td>
<td>Autologous chondrocyte implantation, knee</td>
</tr>
<tr>
<td>27415</td>
<td>Osteochondral allograft, knee, open</td>
</tr>
<tr>
<td>27416</td>
<td>Osteochondral allograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])</td>
</tr>
<tr>
<td>29866</td>
<td>Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft[s])</td>
</tr>
<tr>
<td>29867</td>
<td>Arthroscopy, knee, surgical; osteochondral autograft (e.g., mosaicplasty)</td>
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</tbody>
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<tr>
<th>HCPCS Codes</th>
<th>Description: Codes Considered Experimental and Investigational</th>
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<tbody>
<tr>
<td>J7330</td>
<td>Autologous cultured chondrocytes, implant</td>
</tr>
<tr>
<td>S2112</td>
<td>Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)</td>
</tr>
</tbody>
</table>

**Limitations:**
The use of autologous chondrocyte transplantation, osteochondral allograft transplantation, and osteochondral autograft transplantation (OATS/mosaicplasty) are considered experimental and investigational for all other joints.

**Clinical Background Information:**
The knee joint is responsible for much of an individual’s weight bearing capability because of its location at the end of two long bones, the femur and the tibia. Weight is distributed throughout the knee joint and pressure is placed on the femoral condyles, trochlea and patella during flexion and extension. Hyaline cartilage covers the articular surface of the knee joints and plays a significant role in decreasing mechanical load and
friction. Disabling knee joint function with pain and swelling can occur when the hyaline cartilage is damaged. Treatment that is unsuccessful can lead to progressive degenerative changes which may lead to total knee replacement. First line options for managing articular defects of the knee include such procedures as debridement, abrasion or arthroplasty subchondral drilling, and microfracture. All of these are considered standard therapies which attempt to restore articular surface by inducing the growth of fibrocartilage into the chondral defect. If these techniques are unsuccessful, other options may include the use of autologous chondrocyte transplantation, osteochondral allograft transplantation and osteochondral autograft transplantation (OATS/mosaicplasty) as treatments to stimulate growth of articular cartilage. All three of these procedures are different and each has specific indications.

The Outerbridge classification is the most recognized system for the evaluation of articular defects of the knee. The Outerbridge classification is as follows:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Criteria</th>
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<tbody>
<tr>
<td>0</td>
<td>Normal</td>
</tr>
<tr>
<td>I</td>
<td>Articular cartilage softening and swelling</td>
</tr>
<tr>
<td>II</td>
<td>Fragmentation and fissuring in an area less than 12 mm (half-inch) diameter</td>
</tr>
<tr>
<td>III</td>
<td>Fragmentation and fissuring in an area greater than 12 mm (half-inch) diameter</td>
</tr>
<tr>
<td>IV</td>
<td>Erosion of cartilage to subchondral bone</td>
</tr>
</tbody>
</table>

Autologous Chondrocyte Transplantation (ACT) is also known as autologous chondrocyte implantation (ACI) is a two-stage surgical procedure where the patient’s own chondrocytes or cartilage cells are removed and grown in a lab to generate more cells. The cultured cells are then re-implanted into the knee at areas where there are cartilage defects with the goal of regenerating cartilage over the next 6-12 months to improve joint function and pain. Carticel, Genzyme Corp. (Cambridge, MA) is the only FDA approved ACT cell-based replacement technology. Carticel is indicated for the repair of symptomatic femoral condyle defects occurring on the medical, lateral or trochlear surfaces that are caused by acute or repetitive trauma, in patients who have failed prior arthroscopic or other surgical repair (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft) procedures.

Osteochondral allograft transplantation is a surgical procedure where bone and cartilage plugs are taken from a cadaver donor and transplanted into the patient’s knee joint to stimulate growth of articular cartilage on the surface of the knee joint. The goal is to maintain the cartilage matrix by providing viable chondrocytes and supporting bone to reduce further damage to the articular surface of the joint and improve the patient’s symptoms. Osteochondral allograft transplants are indicated for patient’s with a full thickness cartilaginous defect (Grade III-IV) of the femoral condyle (medial, lateral or trochlea) caused by acute or repetitive trauma in patients who have persistent symptoms.
of disabling localized knee pain for at least 6 months and have failed to respond to conservative treatment (e.g., physical therapy, medications).

Osteochondral autograft transplantation (OATS) and mosaicplasty are surgical procedures where bone and cartilage plugs are taken from low weight bearing surfaces of the patient’s joint and inserted into the affected area of the same patient to stimulate growth of articular cartilage on the surface of the knee joint. OATS involves the transplantation of a single cartilage plug into the affected area and mosaicplasty involves using multiple small cartilage plugs that are inserted into the affected area to create a mosaic of islands of hyaline cartilage. The goal is to resurface the affected area of the joint and improve the patient’s symptoms. OATS and mosaicplasty are indicated for patient’s with a full thickness cartilaginous defect (Grade III-IV) of the femoral condyle (medial, lateral or trochlea) caused by acute or repetitive trauma in patients who have persistent symptoms of disabling localized knee pain for at least six (6) months and have failed to respond to conservative treatment (e.g., physical therapy, medications).

Ideally, candidates for any of the above three procedures should have a stable and aligned knee and are willing and compliant with participation in a vigorous rehabilitation program. A history of osteoarthritis, active infection, or bone cancer in the affected limb are considered contraindications to these procedures.

Autologous chondrocyte transplantation, osteochondral autografts and allografts are also being used as a treatment for articular disorders of the ankle (talus), elbow and shoulder. At the current time the peer reviewed published scientific evidence is insufficient to permit conclusions about safety and efficacy of these procedures for use in joints other than the knee.

References:


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Policy History:

Original Effective Date: 11/01/08
*Effective Date for Commercial is 01/01/12

Date of Review/Revision:
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07/28/09: Annual review, no changes, updated references
07/01/10: Annual review, no changes, updated references
07/01/11: Annual review, no changes, updated references
07/01/12: Annual review and updated references. No change made to applicable code list. Revised list of conservative treatment options. Added language in clinical criteria that states “acute trauma may result from falls, sports, and other sources of impact while repetitive trauma may include overuse.” Changed criteria for all three procedure types from “no history of bone cancer in the affected limb” to “no history of cancer in the bone, cartilage, fat, or muscle of the treated limb.” Added note in Description of Item or Service with recommendations on age and BMI of member seeking surgical procedure. Added language in Applicable Code section

Last Review Date:
07/01/12

Next Review Date:
07/01/13

Approval Dates:
Regulatory Approval:  N/A
Internal Approval:
07/08/08:  MPCTAC
07/22/08:  UMC
08/13/08:  QIC
07/28/09:  MPCTAC & UMC
08/26/09:  QIC
08/18/10:  MPCTAC
09/22/10:  QIC
08/17/11:  MPCTAC
09/28/11:  QIC
07/18/12:  MPCTAC
08/22/12:  QIC

Authorizing Entity:
QIC

IMPORTANT NOTE: Not all services are covered for all products or employer groups. This medical policy expresses the Plan's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. The Plan has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered or not covered, this conclusion is not based upon the terms of a member’s particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all services that are determined to

BMC HealthNet Plan – Osteochondral Defects
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