Medical Policy

Osteochondral Treatments for Defects of the Knee

Policy Number: OCA 3.965
Version Number: 10
Version Effective Date: 01/01/16

Product Applicability

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
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<tbody>
<tr>
<td>☑ New Hampshire Medicaid</td>
<td>☑ MassHealth</td>
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<tr>
<td>☑ NH Health Protection Program</td>
<td>☑ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
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<tr>
<td></td>
<td>☑ Senior Care Options ◊</td>
</tr>
</tbody>
</table>

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers autologous chondrocyte transplantation (ACT), osteochondral autograft transplantation (OATS/mosaicplasty), and osteochondral allograft transplantation procedures for osteochondral defects of the knee to be medically necessary when Plan medical criteria are met. Autologous chondrocyte transplantation (ACT), osteochondral allograft transplantation, and/or osteochondral autograft transplantation (OATS/ mosaicplasty) for other joints, including but not limited to the ankle (talus), are considered experimental and investigational. Prior authorization is required.

Osteochondral Treatments for Defects of the Knee

Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Description of Item or Service

Autologous Chondrocyte Implantation (ACI)/Autologous Chondrocyte Transplantation (ACT): A two-stage surgical procedure by which 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 reduce pain.

Osteochondral Allograft Transplantation: A surgical procedure by which 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 Transfer System (OATS)/Osteochondral Autograft Transplantation (OATS) and Mosaicplasty: Surgical procedures by which 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 technique for repairing articular cartilage that has been damaged by trauma. OATS involves transplanting one or more cartilage plugs and mosaicplasty involves transplanting several cartilage plugs.

Medical Policy Statement

The Plan considers autologous chondrocyte transplantation (ACT), osteochondral autograft transplantation (OATS/mosaicplasty), or osteochondral allograft transplantation procedures to be medically necessary for osteochondral defects of the knee when the following applicable criteria are met and documented in the member’s medical record, as specified below in BOTH item 1 (member criteria) and item 2 (procedure-specific criteria):

1. **Member Criteria:**

   ALL of the following member criteria are met, as specified below in items a through k:

   a. Skeletally mature adult between 18 and 55 years of age on the date of service. If an adolescent member is evaluated, s/he should be skeletally mature with documented closure of growth plates (e.g., 15 years or older); AND

   b. Not considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery; AND
c. Persistent symptoms of disabling, localized knee pain have been present for at least six (6) months; AND

d. Failure to respond to at least (6) months of conservative treatment (e.g., physical therapy, braces, and/or non-steroidal anti-inflammatory drugs); AND

e. Body mass index (BMI) is less than or equal to 35 (for improved surgical outcomes by decreasing stress from weight-bearing on the joint); AND

f. Condition consists of 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; AND

g. Absence of knee osteoarthritis; AND

h. Absence of active infection; AND

i. Motivation and willingness to comply with a rigorous rehabilitation program; AND

j. No history of cancer in the bone, cartilage, fat or muscle of the treated limb; AND

k. All procedure-specific criteria are met, as specified below; AND

2. Procedure-Specific Criteria:

The applicable procedure-specific criteria are met, as specified below as item a, item b, or item c:

a. **Autologous Chondrocyte Transplantation (ACT)/Autologous Chondrocyte Implantation (ACI):**

ALL of the following criteria are met for autologous chondrocyte transplantation (ACT)/autologous chondrocyte implantation (ACI), as specified below in items (1) through (7):

(1) Inadequate response to prior arthroscopic or other surgical repair (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft); AND

(2) Cartilage defect of the femoral condyle measuring 1 to 12 cm squared (after debridement to healthy tissue); AND

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(3) Absence of generalized tibial chondromalacia; AND

(4) Absence of known history of hypersensitivity to gentamicin, other aminoglycosides or materials of bovine origin; AND

(5) Absence of meniscal pathology; AND

(6) Stable and aligned knee (corrective procedures may be performed in combination with or prior to ACT); AND

(7) Normal articular cartilage at lesion border; OR

b. **Osteochondral Allograft Transplantation:**

ALL of the following criteria are met for osteochondral allograft transplantation, as specified below in items (1) through (4):

(1) Cartilage defect measuring greater than or equal to 2 cm squared; AND

(2) Stable knee with intact, fully functional menisci and ligaments; AND

(3) Normal knee alignment; AND

(4) Normal joint space; OR

c. **Osteochondral Autograft Transplantation (OATS/Mosaicplasty):**

ALL of the following criteria are met for osteochondral autograft transplantation (OATS/mosaicplasty), as specified below in items (1) through (4):

(1) Cartilage defect size is between 1.0 to 2.5 cm squared in total area; AND

(2) A stable knee with intact, fully functional menisci and ligaments; AND

(3) Normal knee alignment; AND

(4) Normal joint space
Limitations

1. Autologous chondrocyte transplantation (ACT), osteochondral allograft transplantation, or osteochondral autograft transplantation (OATS/mosaicplasty) is considered experimental and investigational for ANY of the following, as specified below in items a through c:

   a. Treatment of a joint other than the knee or when Plan criteria are not met; OR

   b. Treatment of patella lesions; OR

   c. Treatment for a member less than age 15 (unless skeletally mature) or older than age 55 on the date of service.

2. The use of synthetic, resorbable polymers as bone filler material for osteochondral articular cartilage defects of the knee is considered experimental and investigational.

3. The use of minced articular cartilage for the repair of osteochondral articular cartilage defects of the knee is considered experimental and investigational.

Definitions

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

**Outerbridge Grading System:** A common classification system used to describe a chondral injury; additional classification systems used to define chondral defects include the International Cartilage Repair Society (ICRS) classification and the Noyes classification. The Outerbridge grading system describes the arthroscopic appearance of cartilage wear. The compartmental wear of the joint space is more accurately assessed by combining the description of the damaged cartilage with the results of radiographic tests and magnetic resonance imaging (MRI). The Outerbridge grading system is classified as follows:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Criteria for Outerbridge Grading System</th>
</tr>
</thead>
<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>
Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

<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 autograft(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 allograft (e.g., mosaicplasty)</td>
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</tbody>
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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
</tr>
</thead>
<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>
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<thead>
<tr>
<th>CPT Code</th>
<th>Description: Code Considered Experimental and Investigational</th>
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<tbody>
<tr>
<td>28446</td>
<td>Open osteochondral autograft, talus (includes obtaining grafts[s])</td>
</tr>
</tbody>
</table>

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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. In the skeletally mature individual, articular cartilage does not heal effectively when injured. Unsuccessful treatment can lead to progressive degenerative changes which may later require a total knee replacement. First line options for managing articular defects of the knee include procedures such as debridement, abrasion, arthroscopic subchondral drilling, and/or microfracture. All these standard therapies 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 (ACT), osteochondral allograft transplantation, or osteochondral autograft transplantation (OATS/mosaicplasty) as a treatment to stimulate growth of articular cartilage. Each of these procedures is different and has its own specific indications.

Carticel®, Genzyme Corp. (Cambridge, MA) is the only FDA-approved cell-based ACT technology. Carticel® is indicated for the repair of symptomatic femoral condyle defects occurring on the medical, lateral, or trochlear weight-bearing surfaces that are caused by acute or repetitive trauma; ACT is used in patients who have failed prior arthroscopic or other surgical repair (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft) procedures. Carticel® is not FDA approved for use in pediatric patients; there is insufficient evidence on the safety or efficacy with children and skeletally immature adolescents. Carticel® is also not FDA approved for use in adults over the age of 65 because of insufficient data of clinical efficacy.

Osteochondral allograft transplant, OATS, or mosaicplasty is indicated for a patient with a full-thickness cartilaginous defect (Grade III-IV) of the femoral condyle (medial, lateral or trochlea) caused by acute or repetitive trauma; a candidate for one of these procedures has had persistent, disabling localized knee pain for at least six (6) months and has failed to respond to conservative treatment (e.g., physical therapy, medications). The goal of each procedure is to resurface the affected area of the joint and improve the patient’s symptoms. Ideally, a candidate for any of the above three (3) procedures should have a stable and aligned knee and is willing and compliant with participation in a vigorous rehabilitation program. A history of osteoarthritis, active infection, or bone cancer in the affected limb is considered a contraindication for each of these procedures.

Synthetic resorbable polymers as bone void fillers or plugs (e.g., PolyGraft™ BGS, TruFit® [cylindrical plug], TruGraft™ [granules]) are available and have been proposed as bone graft substitute materials. Human studies are limited and poor clinical outcomes have been documented, including persistent pain, functional deficits, and failure of graft incorporation. The medical literature is insufficient to support the use of synthetic resorbable polymers for this indication.
Minced cartilage repair is a single-stage procedure that uses minced pieces of cartilage seeded over a scaffold (resorbable copolymer foam) or uses a fibrin adhesive layer (developed from cartilage tissue mixed with fibrin glue adhesive) which allows for even distribution of the chondrocytes to expand within the defect, providing structural and mechanical protection. The minced cartilage technique requires less donor tissue for the repair. Examples of this technology included the cartilage autograft implantation system (CAIS) developed by DePuy Mitek (Raynham, MA) and the DeNOVO NT Graft ("Natural Tissue Graft"; Zimmer Inc., Warsaw, IN/ISTO Technologies Inc. St Louis, MO). Additional clinical studies are needed to establish the safety and efficacy of minced cartilage repair.

Autologous chondrocyte transplantation (ACT), osteochondral autografts and allografts have been reported as a treatment for articular disorders other than the knee, including the ankle (talus), elbow, and shoulder. At the present time, the peer-reviewed 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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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>11/01/08 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>MPCTAC . QIC, and Utilization Management Committee (UMC)</td>
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<td>Internal Approval: 07/08/08: MPCTAC</td>
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<tr>
<td>07/22/08: UMC</td>
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<tr>
<td>08/13/08: QIC</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13

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<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>07/01/10</td>
<td>No changes except updated references.</td>
<td>Version 3</td>
<td>08/18/10: MPCTAC 09/22/10: QIC</td>
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<tr>
<td>07/01/11</td>
<td>No changes except updated references.</td>
<td>Version 4</td>
<td>08/17/11: MPCTAC 09/28/11: QIC</td>
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<tr>
<td>07/01/12</td>
<td>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.</td>
<td>Version 5</td>
<td>07/18/12: MPCTAC 08/22/12: QIC</td>
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<tr>
<td>07/30/12</td>
<td>Off cycle review for Well Sense Health Plan, revised Summary statement, reformatted Medical Policy Statement section, deleted reference to Carticel product.</td>
<td>Version 6</td>
<td>08/03/12: MPCTAC 09/05/12: QIC</td>
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<tr>
<td>07/01/13</td>
<td>Review for effective date 11/01/13. Revised text in Description of Item or Service section. Removed duplicate text in the Clinical Background Information section and added information on Carticel®, minced cartilage repair, and synthetic resorbable polymers. Moved medical guidelines (related to skeletal maturing and BMI) from Description of Item or Service to the Medical Policy Statement</td>
<td>11/01/13 Version 7</td>
<td>07/17/13: MPCTAC 08/15/13: QIC</td>
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<tr>
<td>Policy Revisions History</td>
<td>04/01/14</td>
<td>05/01/15</td>
<td>11/25/15</td>
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<tr>
<td>Review for effective date 08/01/14. Revised Summary, Description of Item or Service, Definitions, and References sections. Revised criteria in the Medical Policy Statement section.</td>
<td>08/01/14 Version 8</td>
<td>05/01/15 Version 9</td>
<td>01/01/16 Version 10</td>
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<tr>
<td>Review for effective date 05/01/15. Updated references. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Administrative changes made to Medical Policy Statement section and Limitation section to clarify criteria.</td>
<td>04/16/14: MPCTAC 05/14/14: QIC</td>
<td>03/18/15: MPCTAC 04/08/15: QIC</td>
<td>11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
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**Last Review Date**

11/25/15

**Next Review Date**

03/01/16

**Authorizing Entity**

QIC

**Other Applicable Policies**

Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12
Medical Policy - *Medically Necessary*, policy number OCA 3.14
Disclaimer Information: +

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.