Knee Cartilage Transplants

Date of Origin: 3/2005            Last Review Date: 08/28/2019            Effective Date: 09/01/2019

Dates Reviewed: 04/2013, 04/2014, 04/2015, 05/2016, 07/2016, 08/2017, 08/2019

Developed By: Medical Necessity Criteria Committee

I. Description

_Algograft transplants_ of the knee are a type of procedure used in the treatment of individuals with symptomatic disabling cartilage injury or disease. This surgical technique can restore knee function in patients with focal articular cartilage defects due to trauma or other conditions such as osteochondritis dissecans. The procedure involves the transplantation of a piece of articular cartilage from a cadaver donor to the damaged surface of the knee.

_Osteochondral autografting_ is a surgical procedure used in an attempt to repair damaged articular cartilage. This type of procedure involves the placement of viable hyaline cartilage grafts into a cartilage defect. The grafts are harvested from a non-weight bearing region of the joint during an open or arthroscopic procedure and then transplanted into a cartilage defect to restore the articular surface of the bone. Osteochondral autografts are performed mainly to treat small and medium-size focal chondral and osteochondral defects of the weight-bearing surfaces of the knee joint. Two forms of osteochondral autografting are mosaicplasty and the osteochondral autograft transplantation system (OATS®) procedure. Although different instrumentation is used in mosaicplasty and OATS® procedures, the underlying principle is similar. These procedures use either multiple osteochondral cores or a single graft, harvested from a nonweight-bearing region of the joint that are autografted into the chondral defect.

_Autologous Chondrocyte Transplantation (ACT)_ or Autologous Chondrocyte Implantation (ACI) is a surgical procedure used to treat isolated full thickness (down to bone) articular cartilage defects of the knee. The first procedure is performed arthroscopically and involves harvesting a small piece of articular cartilage from the patient’s knee. The cartilage biopsy is then sent to a laboratory where it is enzymatically treated so as to isolate chondrocytes (cartilage producing cells of the body). The chondrocytes are then expanded in number and used later for implantation. The second stage involves arthrotomy whereby a small patch is sewn over the articular cartilage defect. The chondrocytes that have been harvested and expanded, are then injected underneath this patch where they adhere to the patient’s knee to form a hyaline-like cartilage which resembles the native joint cartilage.
II. Criteria:

A. Cartilage Transplants of the knee will be covered to plan limitations for 1 or more of the following:

   a. Meniscal Allograft Transplantation is considered medically necessary when ALL of the following criteria are met **CWQI: HCS-0048D**
      i. The patient has significant knee pain that interferes with age appropriate activities of daily living and/or demands of employment
      ii. Prior significant trauma resulting in an irreparable meniscal tear or has undergone a meniscectomy where at least 50% of the meniscus has been removed
      iii. Any ONE of these findings following physical examination:
         1. Limited range of motion
         2. Evidence of joint swelling
         3. Joint line tenderness
      iv. Failure of provider-directed non-surgical management for at least 3 months in duration
      v. Patient has a Body Mass Index (BMI) of 35 or less
      vi. Age 49 years or younger

   b. Meniscal allograft transplantation is considered NOT medically necessary for any other indication or condition, including when EITHER of the following criteria is present:
      i. Upon standing radiographs, individual demonstrates osteoarthritic change in the knee including joint space narrowing and osteophytes which is classified by the Kellgren-Lawrence Scale as Grade III or IV
      ii. Upon MRI, individual demonstrates articular degeneration in affected compartment which is classified by the Modified Outerbridge Scale as Grade III or IV

   c. Osteochondral Allograft/Autograft Transplantation Systems (OATS)/Mosaicplasty
      i. Osteochondral Allograft/Autograft Transplantation (OATS)/mosaicplasty will be covered to plan limitations when ALL of the following criteria have been met:
         1. The patient has significant knee pain that interferes with age appropriate activities of daily living and/or demands of employment
         2. Presence of BOTH of the following a physical examination
            a. A stable knee with intact or reconstructed ligaments (ACL or PCL)
            b. Normal tibial-femoral and/or patella-femoral alignment
         3. Failure of provider-directed non-surgical management for at least 3 months in duration
         4. Full-thickness distal femoral articular surface (i.e. medial condyle, lateral condyle, or trochlea) and/or patellar chondral defect that has been identified during an MRI or CT arthrogram, or during an arthroscopy and classified by the Modified Outerbridge Scale as Grade III or Grade IV
         5. EITHER of the following:
            a. Osteochondral autograft transplants and mosaicplasty:
               i. Small (less than or equal to 2.5 cm² total) chondral defects with sharp, definite borders surrounded by normal-appearing cartilage
            b. Osteochondral allograft transplant:
i. Larger (less than or equal to 10.0 cm² total) chondral defects with sharp definite borders surrounded by normal appearing hyaline cartilage

6. Previous arthroscopic or other traditional surgical procedure (i.e., microfracture, drilling, abrasion, osteochondral graft) has resulted in an unsatisfactory outcome

7. Absence of inflammatory arthritis or other systemic disease affecting the joints

8. Minimal to absent osteoarthritic changes in the surrounding articular cartilage (e.g. Kellgren-Lawrence Grade 2 or less)

9. Normal articular cartilage at the lesion border (contained lesion)

10. For femoral and patellar chondral lesions, absence of a corresponding “kissing lesions” with a Modified Outerbridge Scale of Grade III or Grade IV of the distal femur (trochlea, condyles), patella or tibia

11. The patient is not considered a candidate for total knee replacement

12. Patient has a body mass index (BMI) of 35 or less

13. Patient is 49 years old or younger

d. Osteochondral allograft/autograft transplantation (OATS)/mosaicplasty of the distal femoral articular or patellar surface is considered experimental and investigational for any other indication or condition.

e. Hybrid autologous chondrocyte implantation performed with osteochondral autograft transfer system (Hybrid ACI/OATS) for the treatment of osteochondral defects is considered experimental and investigational.

f. **Autologous Chondrocyte Transplantation (ACT)** or Autologous Chondrocyte Implantation (ACI) *(using the MACI™ implant)* (CWQI: HCS-0048B) will be covered to plan limitations for treatment of symptomatic single or multiple full-thickness cartilage defects of the distal femoral articular surface (i.e., medial condyle, lateral condyle or trochlea) and/or patella caused by acute or repetitive trauma when ALL of the following criteria are met:

   i. The patient has significant knee pain that interferes with age appropriate activities of daily living and/or demands of employment

   ii. Presence of both of the following on physical examination:

      1. A stable knee with intact or reconstructed ligaments (ACL or PCL)
      2. Normal tibial-femoral and/or patella-femoral alignment

   iii. Failure of provider-directed non-surgical management for at least 3 months in duration

   iv. Full-thickness distal femoral articular surface (i.e. medial condyle, lateral condyle or trochlea) and/or patellar chondral defect of 1-10 cm² in size that has been identified during an MRI or CT arthrogram, or during an arthroscopy and classified by the Modified Outerbridge Scale as Grade III or Grade IV

   v. Absence of osteochondritis dissecans (OCD) lesion that requires bone grafting

   vi. Absence of inflammatory arthritis or other systemic disease affecting the joints

   vii. Minimal to absent osteoarthritic changes in the surrounding articular cartilage (e.g. Kellgren-Lawrence Grade 2 or less)

   viii. Normal articular cartilage at the lesion border (contained lesion)
ix. For femoral and patellar chondral lesions, absence of a corresponding “kissing lesion” with a Modified Outerbridge Scale of Grade III or Grade IV of the distal femur (trochlea, condyles), patella or tibia
x. Patient has a Body Mass Index 35 or less
xi. Age 15-55 years

Autologous chondrocyte implantation is considered NOT medically necessary for any other indication or condition, including when any of the following criteria are present:
i. Any knee joint surgery within six (6) months before screening excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant
ii. Modified Outerbridge Scale Grade III or IV defect(s) on the patella or tibia
iii. Presence of Kellgren-Lawrence Grade 3 or 4 osteoarthritic changes in the surrounding articular cartilage
iv. Total meniscectomy, meniscal allograft, or bucket-handle tear or displaced tear requiring > 50% removal of the meniscus in the target knee
v. Septic arthritis within one (1) year before screening
vi. Known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin
vii. Uncorrected congenital blood coagulation disorders
viii. Cruciate ligament instability

Hybrid autologous chondrocyte implantation performed with osteochondral autograft transfer system (Hybrid ACI/OATS) for the treatment of osteochondral defects is considered experimental and investigational.

*Note: The Outerbridge classification system facilitates an objective description of chondral damage in the knee. Classifications are from a grade 0 to grade IV.

- Grade 0: Normal cartilage
- Grade I: Cartilage with swelling and softening
- Grade II: Partial thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter
- Grade III: Fissuring to the level of subchondral bone in an area with a diameter greater than 1.5 cm
- Grade IV: Exposed subchondral bone

III. Information Submitted with the Prior Authorization Request:
1. Clinical records from treating physician, including history and physical
2. Documentation of conservative treatment tried and failed
3. Appropriate X-rays, MRI, CT or other diagnostic imaging study report
IV. CPT or HCPC codes covered:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>27407</td>
<td>Repair, primary, torn ligament and/or capsule, knee; cruciate</td>
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<tr>
<td>27412</td>
<td>Autologous chondrocyte implantation, knee</td>
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<tr>
<td>27415</td>
<td>Osteochondral allograft, knee, open</td>
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<td>27416</td>
<td>Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s]) [except to repair chondral defects of the patella] [excludes synthetic resorbable polymers]</td>
</tr>
<tr>
<td>27427</td>
<td>Ligamentous reconstruction (augmentation), knee; extra-articular</td>
</tr>
<tr>
<td>27428</td>
<td>Ligamentous reconstruction (augmentation), knee; intra-articular (open)</td>
</tr>
<tr>
<td>27429</td>
<td>Ligamentous reconstruction (augmentation), knee; intra-articular (open) and extra-articular</td>
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<tr>
<td>29866</td>
<td>Arthroscopy, knee, surgical; implantation of osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of autografts) [except to repair chondral defects of the patella] [excludes synthetic resorbable polymers]</td>
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<tr>
<td>29867</td>
<td>Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)</td>
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<tr>
<td>29868</td>
<td>Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral</td>
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<td>29870</td>
<td>Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)</td>
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<tr>
<td>J7330</td>
<td>Autologous cultured chondrocytes, implant</td>
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<tr>
<td>S2112</td>
<td>Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)</td>
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V. Annual Review History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Revisions</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>04/2013</td>
<td>Annual Review: Added table with review date, revisions, and effective date.</td>
<td>04/24/2013</td>
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<td>04/2014</td>
<td>Annual Review: No changes</td>
<td>04/30/2014</td>
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<td>04/2015</td>
<td>Annual Review: No changes</td>
<td>04/25/2015</td>
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<tr>
<td>05/2016</td>
<td>Annual Review: Added criteria for OATS, and minor wording and format changes</td>
<td>05/26/2016</td>
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<tr>
<td>7/2016</td>
<td>Reformatted, Updated criteria, codes, separated into 4 separate criteria for each type to load in CWQI.</td>
<td>08/31/2016</td>
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<td>08/2017</td>
<td>Annual Review: No changes; changed to new template</td>
<td>08/23/2017</td>
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<tr>
<td>08/2019</td>
<td>Annual Review: Reformatted and updated criteria, to provide clarity on requirements for coverage and removed duplicated language</td>
<td>09/01/2019</td>
</tr>
</tbody>
</table>
VI. References

22. Washington University Physicians. Autologous chondrocyte implantation
   https://www.ortho.wustl.edu/content/Patient-Care/2888/Services/Sports-Medicine/Overview/Knee/Autologous-Chondrocyte-Implantation.aspx
23. Physician Advisors

Appendix 1 – Applicable ICD10 codes:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>M22.2X1 - M22.3X9</td>
<td>Patellofemoral disorders and other derangements of patella [including lateral, medial, anterior and posterior ligaments]</td>
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<tr>
<td>M22.8X1 - M22.8X9</td>
<td>Other disorders of patella [including lateral, medial, anterior and posterior ligaments]</td>
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<tr>
<td>M23.00-M23.92</td>
<td>Internal derangement of knee [articular cartilage defect]</td>
</tr>
<tr>
<td>M23.601 - M23.8X9</td>
<td>Other spontaneous disruption of ligament(s) of knee and other internal derangements of knee [including lateral, medial, anterior and posterior ligaments]</td>
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<tr>
<td>M25.861-M25.869</td>
<td>Other specified joint disorders, knee [articular cartilage of knee]</td>
</tr>
<tr>
<td>M93.261-M93.269</td>
<td>Osteochondritis of knee</td>
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Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

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<th>Jurisdiction(s): 5, 8</th>
<th>NCD/LCD Document (s):</th>
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<tr>
<td>Noridian Local Coverage Determination (LCD) Non-covered Services (L35008) – CPT 28446</td>
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<td><a href="https://med.noridianmedicare.com/documents/10546/6990983/Non-Covered+Services+LCD">https://med.noridianmedicare.com/documents/10546/6990983/Non-Covered+Services+LCD</a></td>
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NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions

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<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
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</thead>
<tbody>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
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