Knee Cartilage Transplants

Date of Origin: 3/2005 **Last Review Date: 08/23/2023** **Effective Date: 09/01/2023**

Dates Reviewed: 04/2013, 04/2014, 04/2015, 05/2016, 07/2016, 08/2017, 08/2019, 10/2019, 08/2020, 09/2021, 07/2022, 08/2023

Developed By: Medical Necessity Criteria Committee

I. Description

Allograft 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 principles are similar. These procedures use either multiple osteochondral cores or a single graft, harvested from a non-weight 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 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/effusion
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 are present:

i. Upon standing radiographs, individual demonstrates osteoarthritic changes in the knee including joint space narrowing and osteophytes which are classified by the Kellgren-Lawrence Scale as Grade III or IV

ii. Upon MRI, an individual demonstrates articular degeneration in the 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 on physical examination
   a. A stable knee with intact or reconstructed ligaments (ACL or PCL) and menisci
      i. Concurrent ligament stabilization or meniscal procedure at the time of OATS would be acceptable
   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 cm^2 total) chondral defects with sharp, definite borders surrounded by normal-appearing hyaline cartilage

b. Osteochondral allograft transplant:

i. Larger (greater than or equal to 10.0 cm^2 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, the absence of 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/arthroplasty
12. Patient has a 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)

a. A concurrent ligament stabilization or meniscal procedure at the time of ACI would be acceptable

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 cm^2 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. Absence of osteoarthritis or generalized tibial chondromalacia
viii. Minimal to absent osteoarthritic changes in the surrounding articular cartilage (e. g. Kellgren-Lawrence Grade 2 or less)
ix. Normal articular cartilage at the lesion border (contained lesion)
x. 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
xi. Patient has a BMI of 35 or less
xii. Age 15-55 years

g. 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

h. Hybrid autologous chondrocyte implantation performed with an 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:

Codes	Description
27407	Repair, primary, torn ligament and/or capsule, knee; cruciate
27412	Autologous chondrocyte implantation, knee
27415	Osteochondral allograft, knee, open
27416	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]
27427	Ligamentous reconstruction (augmentation), knee; extra-articular
27428	Ligamentous reconstruction (augmentation), knee; intra-articular (open)
27429	Ligamentous reconstruction (augmentation), knee; intra-articular (open) and extra-articular
29866	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]
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral
29870	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)
J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

V. Annual Review History

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

10/2019	Update: Corrected c.i.5.b.i. 'greater than or equal to 10.0 cm^2 total' to ensure clarity of the requirement	10/09/2019
08/2020	Annual Review: No changes	09/01/2020
08/2021	Annual Review: No changes	09/01/2021
07/2022	Annual Review: updates to align with eviCore, added menisci, Absence of osteoarthritis or generalized tibial chondromalacia	08/01/2022
08/2023	Annual Review: updates to align with eviCore- added 'A concurrent ligament stabilization or meniscal procedure at the time of ACI would be acceptable'	09/01/2023

VI. References

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23. Physician Advisors

Appendix 1 – Applicable Diagnosis Codes:

Codes	Description
M22.2X1 - M22.3X9	Patellofemoral disorders and other derangements of patella [including lateral, medial, anterior and posterior ligaments]
M22.8X1 - M22.8X9	Other disorders of patella [including lateral, medial, anterior and posterior ligaments]
M23.00-M23.92	Internal derangement of knee [articular cartilage defect]
M23.601 - M23.8X9	Other spontaneous disruption of ligament(s) of knee and other internal derangements of knee [including lateral, medial, anterior and posterior ligaments]
M25.861-M25.869	Other specified joint disorders, knee [articular cartilage of knee]
M93.261-M93.269	Osteochondritis of knee

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):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
Noridian Local Coverage Determination (LCD) Non-covered Services (L35008) – CPT 28446	
https://med.noridianmedicare.com/documents/10546/6990983/Non-Covered+Services+LCD	

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC