Medical Necessity Guidelines:
Autologous Chondrocyte Implant of the Knee

Effective: July 20, 2017


Applies to:
☒ Tufts Health Plan Commercial Plans products; Fax: 617.972.9409
☒ Tufts Health Public Plans products
   ☑ Tufts Health Direct – Health Connector; Fax: 888.415.9055
   ☑ Tufts Health Together – A MassHealth Plan; Fax: 888.415.9055
   ☐ Tufts Health Unify – OneCare Plan; Fax: 781.393.2607
   ☑ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404
☒ Tufts Health Freedom Plan products; Fax: 617.972.9409

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

OVERVIEW
Autologous chondrocyte implantation utilizes a Member’s own cartilage cells to repair traumatic damage to articular cartilage, thereby improving joint function and reducing pain. The procedure involves the collection and ex vivo culture of articular cells, which are then implanted into the cartilage defect where they contribute to regeneration and repair of the articular surface.

COVERAGE GUIDELINES
1. Tufts Health Plan may authorize coverage for autologous chondrocyte implant (ACI) of the knee for defects involving the weight bearing area of the femoral condyle (medial, lateral, or trochlear):
   A. As a first line procedure for Members when ALL of the following criteria are met:
      1) Age ≥18 and ≤55
      2) Isolated, full thickness defect >4 cm² involving the weight bearing area of the femoral condyle (medial, lateral, or trochlear), based upon the operative notes from diagnostic arthroscopy
      3) Symptoms interfere with the ability to maintain activities of daily living
   B. As a second line procedure for Members when ALL of the following criteria are met:
      1) Age ≥18 and ≤55
      2) Isolated, full thickness defect >2.5 cm² and ≤4 cm² involving the weight bearing area of the femoral condyle (medial, lateral, or trochlear), based upon the operative notes from diagnostic arthroscopy
      3) Failed prior surgical repair* procedure directed at the femoral condylar lesion, with persistent disability associated with pain, effusion and/or locking despite an appropriate post-operative rehabilitation program

   *For the purposes of these criteria, acceptable prior surgical repair procedures include:
   - Abrasion arthroplasty by drilling or microfracture
   - Osteochondral autograft or allograft

2. Tufts Health Plan may authorize coverage for autologous chondrocyte implant (ACI) of the knee for patellar lesions in Members when ALL of the following criteria are met:
   A. Age ≥18 and ≤55
   B. Isolated patellar lesion
   C. A retracking procedure is planned at the same time (e.g., tibial osteotomy)
   D. Failed corticosteroid injection
   E. Failure of a 6 week course of PT following lesion debridement and obtaining the cells for culture
   F. Member not actively taking narcotics or smoking tobacco products
<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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<tbody>
<tr>
<td>Grade 1</td>
<td>Doubtful narrowing of joint space and possible osteophytic lipping</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Definite osteophytes, definite narrowing of joint space</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Moderate multiple osteophytes, definite narrowing of joints space, some sclerosis and possible deformity of bone contour</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour</td>
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**Lawrence Kellgren Grading Scale**  
Accessed on March 11, 2014 at:  
www.swedankle.se/pdf/instrument/Kellgren_and_Lawrence_grading_scale.pdf

**LIMITATIONS**  
Member will not be considered a candidate for autologous chondrocyte implant of the knee if he/she has one or more of the following:  
- A tibial defect  
- Grade III or IV chondromalacia of the tibial surface  
- Osteoarthritis, instability, abnormal loading or tracking of the knee, unless repair done simultaneously  
- Member has severe osteoarthritis of the knee (Kellgren-Lawrence grade 3 or 4)  
- Requested procedure is for joint other than the knee.

**CODES**  
The following CPT/ HCPCS code(s) require prior authorization:  

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>27412</td>
<td>Autologous chondrocyte implantation, knee</td>
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<tr>
<td>S2112</td>
<td>Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)</td>
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<tr>
<td>J7330</td>
<td>Autologous cultured chondrocytes, implant</td>
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**REFERENCES**  

**APPROVAL HISTORY**  
February 1999: Reviewed by the Clinical Coverage Criteria Committee  
Subsequent endorsement date(s) and changes made:  
- November 2001: No changes
• November 2002: No changes
• October 7, 2003: Reviewed, renewed, and updated to new format only.
• October 15, 2004: Reviewed and renewed.
• October 21, 2005: Addition of coverage for osteoarthritis, instability, abnormal loading or tracking of the knee, when repair done simultaneously.
• October 16, 2006: Reviewed and renewed without changes.
• February 28, 2007: Reviewed and renewed without changes.
• February 27, 2008: Reviewed and renewed without changes.
• March 16, 2009: Reviewed and renewed without changes.
• April 2010: Reviewed at Medical Specialty Policy advisory Committee (MSPAC), no changes.
• March 2011: Reviewed at MSPAC: First and Second line treatment categories added; removed debridement and rehab as acceptable prior surgical repairs. Effective October 1, 2011.
• August 8, 2012: Reviewed at Integrated Medical Policy Advisory Committee (IMPAC), symptoms clarified.
• September 12, 2012: Reviewed at IMPAC and renewed without changes.
• October 16, 2013: Reviewed at IMPAC and renewed without changes.
• March 12, 2014: Reviewed by IMPAC for a July 1, 2014 effective date. The limitation of coverage for patellar lesions was removed. Specific criteria for the coverage of ACI for patellar lesions were added.
• October 8, 2014: Reviewed by IMPAC, renewed without changes.
• September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
• September 9, 2015: Reviewed by IMPAC, renewed without changes.
• June 8, 2016: Reviewed by IMPAC. For effective date October 1, 2016, change of criteria to include ages ≥18 and <65 and to allow ACI as first line procedure for femoral condyle lesions >4 cm².
• August 10, 2016: Reviewed by IMPAC, renewed without changes.
• March 15, 2017: Reviewed by IMPAC. Limitations added due to implant product transition from Carticel® to MACI®.
• July 20, 2017: Reviewed by IMPAC. Change in criteria and limitations to coincide with market replacement of Carticel with MACI.
• July 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to the fully insured Commercial and Medicaid products when Tufts Health Plan conducts utilization review unless otherwise noted in this guideline or in the Member's benefit document, and may apply to Tufts Health Unify to the same extent as Tufts Health Together. This guideline does not apply to Tufts Medicare Preferred HMO, Tufts Health Plan Senior Care Options or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates or other requirements will take precedence. For CareLinkSM Members, Cigna conducts utilization review so Cigna’s medical necessity guidelines, rather than these guidelines, will apply.
Treating providers are solely responsible for the medical advice and treatment of Members. The use of these guidelines is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.