TITLE: AUTOLOGOUS CULTURED CHONDROCYTE TRANSPLANTATION FOR THE KNEE

EFFECTIVE DATE: November 20, 2017

This policy was developed with input from specialists in orthopedic surgery and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY
These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE
To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of autologous cultured chondrocyte transplantation for the knee. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND
Definitions
A. Autologous chondrocyte transplantation (ACT), also known as autologous chondrocyte implantation (ACI), is a two-step surgical procedure for treatment of articular defects of the knee. First, an arthroscopy is performed to debride the defect. At this time, a sample of healthy knee cartilage is removed from the patient and sent to a specialized laboratory to be cultured into additional chondrocytes. Second, an open arthrotomy is performed to implant the cultured cells over the defect. This is followed by physical rehabilitation. The goal is to restore resilient, durable cartilage at the site of injury.

In first generation ACT, the cultured cells are injected under a periosteal membrane that is usually taken from the tibia of the patient and sutured over the knee defect. In second- and third-generation ACT, the cultured cells are injected under or grown attached to a synthetic membrane or scaffold that is sutured over or adhered to the knee defect.

ACT products that have received U.S. Food and Drug Administration (FDA) approval include:
1. Carticel (Vericel Corp.) was licensed on August 22, 1997. Carticel is used in first-generation ACT procedures. Vericel plans to phase out Carticel now that MACI, a later-generation product, has been FDA approved.
2. ACI-Maix collagen membrane (Vericel Corp) was licensed on December 13, 2016. Also known by the trade name, MACI. MACI is used in second- and third-generation ACT procedures.

B. Cartilage is a stiff and inflexible connective tissue found in many areas in the body of humans, including the joints between bones; the knee, elbow, and ankle; the rib cage and intervertebral discs; the ear and nose; and the bronchial tubes. Cartilage is classified in three categories according to the predominant component in each, and each type is naturally occurring in specified parts of the body. These categories are: (1) elastic cartilage (e.g., outer ear, larynx, epiglottis), (2) hyaline cartilage (e.g., articular surface of bones, ventral ends of ribs, the larynx and trachea, bronchi) and (3) fibrocartilage (e.g., pubic symphysis, intervertebral discs, meniscus, certain healed fractures/healed articular defects).
C. **Chondrocytes** are polymorphic cells that form the cartilage of the body. Each cell contains a nucleus, a relatively large amount of clear cytoplasm, and organelles. The organization of chondrocytes within cartilage differs depending upon the type of cartilage and where in the tissue they are found.

D. **Condromalacia** is breakdown and softening of the cartilage underneath the knee cap, which results in swelling and pain in the knee. Multiple scales are available to grade cartilage damage. See appendix 1 for the Outerbridge Classification.

E. **Femoral condyles** are the large flared prominences on the distal end of the femur, identified as lateral and medical femoral condyles. They are covered with a thick layer of hyaline cartilage and articulate with the patella and the tibia at the knee joint.

F. **Hyaline cartilage** is semi-transparent, opalescent cartilage consisting of cells that synthesize a surrounding matrix of hyaluronic acid, collagen, and protein with cavities in which chondrocytes form. It forms most of the fetal skeleton and is found in the trachea, larynx, and joint surfaces of adults. Damaged hyaline cartilage joints normally fail to heal on their own and the damage is associated with pain, functional loss and disability. It can also lead to disabling osteoarthritis.

G. An **osteochondral articular defect** occurs when a section of joint cartilage is eroded and separates from the bone surface, leaving a depression on the articulating surface of the bone. The margin of the depression generally contains healthy cartilage that can support the grafting of transplanted tissue. The separated cartilage pieces are loose bodies freely moving around within the joint space and require removal prior to ACT.

H. **Outerbridge Classification** is a grading system for joint cartilage breakdown:
- Grade 0: normal cartilage
- Grade I: cartilage with softening and swelling
- Grade II: a 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 more than 1.5 cm
- Grade IV: exposed subchondral bone

I. **Periosteum** is a dense fibrous membrane covering the surface of bones (except in the articulating surfaces in joints) serving as an attachment for tendons and muscles. It is richly supplied with nerve fibers, blood vessels, and lymph vessels. In ACT procedures, the periosteal flap is usually obtained by removing a small section of periosteum from the upper, non-articulating surface of the proximal medial tibia.

J. **Post-surgical rehabilitation program** includes, but is not limited to, (1) non-weight bearing for eight weeks, (2) use of continuous passive motion (CPM) therapy for eight weeks, (3) eight-to-16 week exercise program, and (4) gradual return to post-surgical physical activity levels (e.g., regular, active sports activities).

K. **Skeletal maturity** occurs when bone growth ceases after puberty and refers to demonstration of fusion of skeletal bones. Females reach skeletal maturity at approximately 16 years of age, while males reach skeletal maturity around 18 years of age. Radiographs of either the knee or of the hand and wrist with subsequent mathematical calculations are often used when exact measurement of skeletal maturity is warranted.

L. **Subchondral bone** is the bone underneath the white joint cartilage.

**BENEFIT CONSIDERATIONS**

1. Prior authorization is **required** for autologous cultured chondrocyte transplantation (ACT) for the knee.
2. Coverage may vary according to the terms of the member's plan document.
3. ACT for any other indication than those listed under Medical Necessity Criteria above, is **investigative and therefore, not eligible for coverage**.
4. If medical necessity criteria are not met as defined in this policy, any associated procedures (e.g., debridement, lavage) will not be covered. This includes, but is not limited to, facility and anesthesia services, professional fees, and associated supplies.
5. If the Medical Necessity and Coverage Criteria are met, Medica staff will authorize benefits within the limits in the member’s plan document.
6. If it appears that the Medical Necessity and Coverage Criteria are not met, the case will be submitted to the medical director or external review for individual consideration. Practitioners are advised of the appeal process in their Medica Provider Administrative Manual.
MEDICAL NECESSITY CRITERIA

I. Indications
ACT is considered medically necessary when documentation in the medical record indicates that all of the following criteria are met:

A. The member:
   1. Has reached skeletal maturity.
   2. Is less than 55 years of age.
   3. Has a body mass index (BMI) less than or equal to 35.
   4. Has persistent symptoms of pain, swelling, and/or knee catching/locking.
   5. Has failed prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty).
   6. Has normal knee biomechanics with intact meniscus, or corrective procedures can be achieved prior to or concurrently with ACT (e.g., osteotomy; ligament reconstruction).
   7. Does not have diffuse osteoarthritis of the knee.
   8. Is able to comply with post-operative weight bearing and activity restrictions and rehabilitation.

B. The lesion is:
   1. A single full thickness (Outerbridge Classification of grade III or IV) articular cartilage defect of the femoral condyle (medial, lateral or trochlea).
   2. There is no corresponding lesion on opposing surface.
   3. Caused by acute or repetitive trauma.
   4. Greater or equal to 2cm².
   5. There is no or minimal bone loss or degenerative changes in the surrounding articular cartilage (e.g., corresponding tibia).
   6. Healthy, normal-appearing hyaline cartilage surrounds the border of the defect.

C. Documentation indicates an FDA approved product is being used.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
- For Medicare members, refer to the following, as applicable at: http://www.cms.hhs.gov/mcd/search.asp

DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Original Effective Date</th>
<th>February 1, 2011</th>
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<tbody>
<tr>
<td>Administrative Updates</td>
<td>05/01/2017</td>
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References:
Pre-11/2015 MPC:
11/2015 MPC:

06/2016 MTAC:

09/2016 MPC:

09/2017 MPC: