GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Autologous chondrocyte transplantation (ACT), also referred to as autologous chondrocyte implantation (ACI), utilizes a patient’s own cells in an effort to repair damage to articular cartilage with the goal of improving joint function and reducing pain. The procedure involves the collection and culture of articular cartilage cells (i.e., chondrocytes) that are then implanted into the cartilage defect with the intent that the cultured cells will contribute to the regeneration and repair of the articular surface.

First-generation Autologous Chondrocyte Implantation
Carticel® (Vericel), a autologous cellular product indicated for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral or trochlea), caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft).

Second- and Third-generation Autologous Chondrocyte Implantation
In December 2016, MACI® (Vericel), a matrix-induced autologous chondrocyte implantation, was approved by FDA for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. MACI® consists of autologous chondrocytes which are cultured onto a bioresorbable porcine-derived collagen membrane. In 2017, production of Carticel was phased out and MACI® is the only ACI product that is available in the United States.

Allograft Tissue Implantation
Juvenile cartilage allograft tissue implantation (eg, DeNovo NT natural tissue graft, DeNovo ET engineered tissue graft) was developed to treat damaged cartilage. The natural tissue graft is an allograft transplantation process that involves transplanting minced juvenile donor cartilage into a cartilage defect using a fibrin adhesive. The engineered tissue is a living tissue graft grown from juvenile chondrocytes. The cells are isolated and expanded in vitro. The expanded cells are cryopreserved in a cell bank from which a large number of grafts can be grown. The cells are applied to defects of the surface joint using a fibrin adhesive.

POLICY
Autologous chondrocyte transplantation (eg, MACI) (27412, J7330, S2112) requires prior authorization for HMO, PPO, Individual Marketplace.

Autologous chondrocyte transplantation (eg, MACI) (27412, J7330) requires prior authorization for Advantage & Elite.

Code S2112 is non-covered for Advantage & Elite.

Juvenile cartilage allograft tissue implantation (eg, DeNovo NT natural tissue graft, DeNovo ET engineered tissue graft) is non-covered for all product lines.

HMO, PPO, Individual Marketplace, Elite, Advantage
Patients are referred for ACT after already having had surgery for an articular cartilage problem. If the patient remains symptomatic, and the patient and the surgeon decide that ACT is the best option, then an arthroscopic biopsy is planned. The ordering physician must supply data, through the medical record, to support the procedure. The following criteria must be met:

1. Age between 15-55 years old
2. BMI less than 35
3. Presence of disabling pain and/or locking knee
4. Focal or isolated articular cartilage defect down to but not through, the subchondral bone affecting the medial, lateral or trochlear femoral condyle
5. Size of cartilage defect greater than 2cm squared
6. Stable knee
7. Absence of inflammatory or infectious process in knee
8. Absence of osteoarthritis
9. Failure of conservative therapy defined as
   - Greater than two months of physical therapy AND
   - Traditional surgical intervention
10. Cooperative and motivated patient for postoperative weight-bearing restriction and commitment to completing post-op rehabilitation

Paramount considers FDA-approved matrix-induced chondrocyte implantation (e.g., MACI (Vericel) autologous cultured chondrocytes on porcine collagen membrane) an equally acceptable alternative to autologous cultured chondrocytes (e.g., Carticel) for the medically necessary indications for autologous chondrocyte implants listed above.

ACT is considered experimental/investigational for any indication not listed above, including, but not limited to the following:
1. Cartilage defects in joints other than the knee (patella is considered separate from the knee joint)
2. Individuals who have had a previous total meniscectomy
3. Individuals with a cartilaginous defect associated with osteoarthritis or inflammatory diseases or where an osteoarthritic or inflammatory process significantly and adversely affects the quality of the peri lesional cartilage
4. Individuals with known history of anaphylaxis to gentamicin or sensitivities to materials of bovine origin
5. Individuals with osteochondritis dissecans (OCD) lesions
6. Initial or first line of surgical therapy

Juvenile cartilage allograft tissue implantation (eg, DeNovo NT natural tissue graft, DeNovo ET engineered tissue graft) is experimental and investigational and therefore non-covered because there is insufficient evidence in the peer-reviewed medical literature of the effectiveness of this procedure.

**CODING/BILLING INFORMATION**
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODES</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>27412</td>
<td>Autologous chondrocyte implantation, knee</td>
</tr>
<tr>
<td>27599</td>
<td>Unlisted procedure, femur or knee</td>
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<table>
<thead>
<tr>
<th>HCPCS CODES</th>
<th>Description</th>
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</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>
</tbody>
</table>

**TAWG REVIEW DATES:**
DeNovo – 06/15/2011, 12/11/2013, 01/23/2015, 01/22/2016, 01/27/2017

**REVISION HISTORY EXPLANATION**
04/18/14: Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG). ACT continues to be covered with prior authorization for all product lines. DeNovo NT Natural Tissue Graft is non-covered for all product lines.
01/23/15: Policy revised to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
01/22/16: PPO will now be required to do prior authorization for ACT (27412). Policy revised to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
01/27/17: Removed invalid code 27410. Code J7330 was added to the policy as covered with prior authorization for all product lines. Code S2112 was added to the policy as covered with prior authorization for HMO, PPO, & Individual Marketplace and non-covered for Advantage & Elite. Policy revised to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
10/27/17: Added information on MACI (autologous cultured chondrocytes on porcine collagen membrane). Paramount considers FDA-approved matrix-induced chondrocyte implantation (e.g., MACI (Vericel) autologous cultured chondrocytes on porcine collagen membrane) an equally acceptable alternative to autologous cultured
chondrocytes (e.g., Carticel) for the medically necessary indications for autologous chondrocyte implants listed above. Policy revised to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Industry Standard Review
Hayes, Inc.