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
Treatment for a focal (i.e., a localized) articular cartilage involves filling a posttraumatic or degenerative nonhealing focal articular cartilage defect with viable hyaline cartilage and supporting bone. Chondral defects are focal areas of articular (hyaline) cartilage injury. Osteochondral defects are focal areas of articular (hyaline) cartilage injury with involvement of the adjacent subchondral bone. Signs and symptoms of damaged both cartilage and bone in the knee joint(s) typically consist of pain, joint swelling, joint stiffness and joint dysfunction.

Varieties of procedures are being developed to resurface articular cartilage defects. Cartilage repair and regeneration is a treatment for joints that have damaged cartilage but are otherwise healthy. Replacing lost knee cartilage, may help restore normal knee function and may delay or even eliminate the need for a knee replacement.

Osteochondral allografts
Osteochondral allografting, also called OATS, osteochondral autograft transfer, or mosaicplasty (harvesting of multiple individual osteochondral cores), involves transplantation of a piece of articular cartilage and attached subchondral bone from a cadaver donor to a damaged region of the articular surface of a joint. Non-autologous mosaicplasty (allografts) receives the graft(s) in small holes drilled and pressed mosaic-like fashion of transplanted hyaline cartilage and fibrocartilage. The proposed advantage of allografting compared to autograft transplantation is the elimination of a harvested bone and cartilage donor graft site.

Osteochondral autografts
Osteochondral autografting transplant involves harvesting cylinders of healthy cartilage and bone from areas of the knee, from the patient, that do not bear much weight. The osteochondral defect then receives the graft(s) through small holes drilled into the lesion. Two related procedures have been utilized: osteochondral autograft transfer system (OATS) or mosaicplasty, Mosaicplasty involves multiple individual osteochondral hyaline cartilage and fibrocartilage cores pressed in a mosaic-like transplantation fashion. Mosaicplasty is performed either by an open approach or arthroscopically. OATS involves the use of a large single plug that fills entire defect. OATS uses an arthroscopic approach.

Autologous Chondrocyte Implantation
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. ACI involves a 3-step treatment, a biopsy, first harvesting a small piece of articular cartilage, through an arthroscopic procedure from a region of healthy knee articular cartilage. Second, the cartilage biopsy is then enzymatically treated in the lab to isolate the cartilage cells, i.e. chondrocytes, and are multiplied using a cell-culture technique to increase in number between three to six weeks’ time. This is a clinically regeneration of tissue (Carticel®, Genzyme Biosurgical, Cambridge, MA or Matrix-Induced Autologous Chondrocyte Implantation (MACI), Vericel Corporation). The culture of chondrocytes are then implanted into the cartilage defect, known as hyaline-like cartilage, with the intent that the cultured cells will contribute to the regeneration and repair of the articular surface. Autologous chondrocyte implantation is performed following failed articular cartilage surgery.

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.

Juvenile cartilage allograft tissue implantation (eg, DeNovo NT natural tissue graft, DeNovo ET engineered tissue graft) was developed to repair damaged articular 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. DeNovo NT Natural Tissue Grafts are single-stage surgery where small pieces of juvenile joint cartilage are implanted into the affected area with a simple surgical technique using a natural sticky glue called fibrin.

The following procedures are considered experimental and investigational because their effectiveness has not been established, not all-inclusive:

- Autologous cartilage chip transplantation for osteochondral repair
- Hybrid autologous chondrocyte implantation performed with osteochondral autograft transfer system (Hybrid ACI/OATS) technique for the treatment of osteochondral defects;
- Osteochondral autografts (OATS, mosaicplasty) of other joints (ankle, elbow, hip, patella, shoulder);
- Osteochondral autograft transplantation for the treatment of Freiberg disease or repair chondral defects of the elbow, patella, shoulder, or joints other than the knee.
- Non-autologous mosaicplasty using resorbable synthetic bone filler materials (including but not limited to plugs and granules) to repair osteochondral defects of the ankle or knee experimental and investigational because their effectiveness has not been established.
- Minced articular cartilage (whether synthetic, allograft or autograft) to repair osteochondral defects of the ankle or knee experimental and investigational because its effectiveness has not been established.
- Synthetic resorbable polymers (e.g., PolyGraft BGS, TruFit [cylindrical plug], TruGraft [granules]) to repair osteochondral articular cartilage defects experimental and investigational because their effectiveness has not been established.
- The combination of adipose-derived stem cells and mosaicplasty for repair of osteochondral defects.
- The combination of autologous chondrocyte implantation and osteochondral autograft transfer for repair of knee osteochondral lesion.
- Any device utilized for this procedure must have FDA approval specific to the indication, otherwise it will be considered investigational.

**POLICY**

| HMO, PPO, Individual Marketplace | Focal Articular Cartilage Repair of the Knee requires prior authorization for procedure codes 27412, 27415, 27416, 29866, 29867, 27599, S2112 |
| Advantage | Focal Articular Cartilage Repair of the Knee requires prior authorization for procedure codes 27412, 27415, 27416, 29866, 29867, 27599. |
| Elite | Focal Articular Cartilage Repair of the Knee requires prior authorization, procedure code 27412. Additionally, effective 1/1/2020, Focal Articular Cartilage Repair of the Knee requires prior authorization for procedures 27415, 27416, 29866, 29867, 27599. |

Procedure 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 |
| Osteochondral autografts |
| Osteochondral autografts is considered medically appropriate if ALL of the following criteria are met |

- Symptomatic focal full-thickness articular cartilage defects down to but not through, the subchondral bone affecting the medial, lateral or trochlear femoral condyle, caused by acute or repetitive trauma; AND
- Cartilage defect measuring 1 – 2.5cm²; AND
- Skeletally mature adult between 15 and 55 years of age on the date of service. If an adolescent member is evaluated, s/he should be skeletally mature with documented closure of growth plates; AND
- The member is not considered a candidate for total knee replacement (i.e., member is under 55 years of age); AND
- Other cartilage repair technique (such as micro-grafting, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to size, location or depth of lesion. For lesions less than 4 cm², inadequate response to a prior surgical procedure (microfracture or abrasive arthroplasty); AND
- The member has disabling symptoms, presence of disabling pain, swelling and/or mechanical symptoms of locking, popping, catching of the knee, limiting ambulation and activities of daily living that have not been relieved by appropriate non-surgical conservative therapies; failure of at least 6 months, including at least two of the following: AND
  - Rest or activity modifications/limitations, ice/heat, protected weight bearing, brace/orthosis
  - Greater than two months of physical therapy
  - Pharmacological treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
  - Corticosteroid injection
  - Traditional surgical intervention (i.e., microfraction, drilling, abrasion, or osteochondral autograft) (diagnostic arthroscopy, lavage, or debridement is not considered adequate to meet this criterion)
- Body mass index (BMI) is less than or equal to 35 kg/m²; AND
- Condition consists of a focal full-thickness cartilaginous defect (Grade III-IV) unipolar lesions on the weight bearing surface of the femoral condyle (medial, lateral or trochlea) or patella caused by acute or repetitive trauma; (acute trauma may result from falls, sports, and other sources of impact while repetitive trauma may include overuse); AND
- Confirmation of defects by radiographs, magnetic resonance imaging (MRI) and arthroscopy; AND
- The member has minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less) and normal appearing hyaline cartilage surrounding the border of the defect; AND
- Absence of knee osteoarthritis, clinically and by X-ray; AND
- Procedure is not being done for treatment of degenerative arthritis (osteoarthritis); AND
- Absence of inflammatory or active infection in knee; AND
- No history of cancer in the bone, cartilage, fat or muscle of the treated limb; AND
- Normal knee biomechanics, or alignment and stability with intact, fully functional menisci and ligaments and normal knee alignment (or achieved concurrently with osteochondral grafting); AND
- Normal joint space on X-ray; AND
- Cooperative and motivated patient for postoperative weight-bearing restriction, activity restriction and commitment to completing post-op rehabilitation

**Osteochondral allografts**

Osteochondral fresh allografting is considered medically appropriate if ALL of the following criteria are met:

- Symptomatic focal full-thickness articular cartilage defects down to but not through, the subchondral bone affecting the medial, lateral or trochlear femoral condyle, caused by acute or repetitive trauma; AND
- Cartilage defect measuring 2.5cm² - 10 cm²; AND
Skeletally mature adult between 15 and 55 years of age on the date of service. If an adolescent member is evaluated, s/he should be skeletally mature with documented closure of growth plates; AND

The member is not considered a candidate for total knee replacement (i.e., member is under 55 years of age); AND

Other cartilage repair technique (such as micro-grafting, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to size, location or depth of lesion. For lesions less than 4 cm², inadequate response to a prior surgical procedure (microfracture or abrasive arthroplasty); AND

The member has disabling symptoms, presence of disabling pain, swelling and/or mechanical symptoms of locking, popping, catching of the knee, limiting ambulation and activities of daily living that have not been relieved by appropriate non-surgical conservative therapies; failure of at least 6 months, including at least two of the following: AND
  o Rest or activity modifications/limitations, ice/heat, protected weight bearing, brace/orthosis
  o Greater than two months of physical therapy
  o Pharmacological treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
  o Corticosteroid injection
    o Traditional surgical intervention (i.e., microfraction, drilling, abrasion, or osteochondral autograft) (diagnostic arthroscopy, lavage, or debridement is not considered adequate to meet this criterion)

Body mass index (BMI) is less than or equal to 35 kg/m²; AND

Condition consists of a focal full-thickness cartilaginous defect (Grade III-IV) unipolar lesions on the weight bearing surface of the femoral condyle (medial, lateral or trochlea) or patella caused by acute or repetitive trauma; (acute trauma may result from falls, sports, and other sources of impact while repetitive trauma may include overuse); AND

Confirmation of defects by radiographs, magnetic resonance imaging (MRI) and arthroscopy; AND

The member has minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less) and normal appearing hyaline cartilage surrounding the border of the defect; AND

Absence of knee osteoarthritis, clinically and by X-ray; AND

Procedure is not being done for treatment of degenerative arthritis (osteoarthritis); AND

Absence of inflammatory or active infection in knee; AND

No history of cancer in the bone, cartilage, fat or muscle of the treated limb; AND

Normal knee biomechanics, or alignment and stability with intact, fully functional menisci and ligaments and normal knee alignment (or achieved concurrently with osteochondral grafting); AND

Normal joint space on X-ray; AND

Cooperative and motivated patient for postoperative weight-bearing restriction, activity restriction and commitment to completing post-op rehabilitation

**Autologous Chondrocyte Implantation**

Autologous Chondrocyte Implantation is considered **medically appropriate** if ALL of the following criteria are met

Symptomatic focal full-thickness articular cartilage defects down to but not through, the subchondral bone affecting the medial, lateral or trochlear femoral condyle, caused by acute or repetitive trauma; AND

Size of cartilage defect greater than 2cm squared; AND
• Skeletally mature adult between 15 and 55 years of age on the date of service. If an adolescent member is evaluated, s/he should be skeletally mature with documented closure of growth plates; AND
• The member is not considered a candidate for total knee replacement (i.e., member is under 55 years of age); AND
• Other cartilage repair technique (such as micro-grafting, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to size, location or depth of lesion. For lesions less than 4 cm², inadequate response to a prior surgical procedure (microfracture or abrasive arthroplasty); AND
• The member has disabling symptoms, presence of disabling pain, swelling and/or mechanical symptoms of locking, popping, catching of the knee, limiting ambulation and activities of daily living that have not been relieved by appropriate non-surgical conservative therapies; failure of at least 6 months, including at least two of the following: AND
  o Rest or activity modifications/limitations, ice/heat, protected weight bearing, brace/orthosis
  o Greater than two months of physical therapy
  o Pharmacological treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
  o Corticosteroid injection
  o Traditional surgical intervention (i.e., microfracture, drilling, abrasion, or osteochondral autograft) (diagnostic arthroscopy, lavage, or debridement is not considered adequate to meet this criterion)
• Body mass index (BMI) is less than or equal to 35 kg/m²; AND
• Condition consists of a focal full-thickness cartilaginous defect (Grade III-IV) unipolar lesions on the weight bearing surface of the femoral condyle (medial, lateral or trochlea) or patella caused by acute or repetitive trauma; (acute trauma may result from falls, sports, and other sources of impact while repetitive trauma may include overuse); AND
• Confirmation of defects by radiographs, magnetic resonance imaging (MRI) and arthroscopy; AND
• The member has minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less) and normal appearing hyaline cartilage surrounding the border of the defect; AND
• Absence of knee osteoarthritis, clinically and by X-ray; AND
• Procedure is not being done for treatment of degenerative arthritis (osteoarthritis); AND
• Absence of inflammatory or active infection in knee; AND
• No history of cancer in the bone, cartilage, fat or muscle of the treated limb; AND
• Normal knee biomechanics, or alignment and stability with intact, fully functional menisci and ligaments and normal knee alignment (or achieved concurrently with osteochondral grafting; AND
• Normal joint space on X-ray; AND
• Cooperative and motivated patient for postoperative weight-bearing restriction, activity 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) (e.g., talar (ankle) lesions, hip and shoulder)
2. Individuals who have had a previous total meniscectomy
3. Individuals with a cartilaginous defect associated with osteoarthritis, rheumatoid arthritis 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.

Advantage
Per the Ohio Department of Medicaid (ODM), provider can request prior authorization to exceed coverage or benefit limits for members under age 21.

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.

CPT CODES

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<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>27415</td>
<td>Osteochondral allograft, knee, open</td>
</tr>
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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>
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<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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<td>29867</td>
<td>Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)</td>
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<tr>
<td>27599</td>
<td>Unlisted procedure, femur or knee, when related to Focal Articular Cartilage Repair of the Knee</td>
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HCPCS CODES

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<tr>
<th>Code</th>
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<tr>
<td>J7330</td>
<td>Autologous cultured chondrocytes, implant [except minced articular cartilage (whether synthetic, allograft or autograft)]</td>
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<tr>
<td>S2112</td>
<td>Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)</td>
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Minced articular cartilage, synthetic allograft or autograft: No specific code

ICD-codes covered if selection criteria are met:

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<tr>
<th>Code</th>
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<tr>
<td>M23.000 - M23.92</td>
<td>Internal derangement of knee [articular cartilage defect]</td>
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<tr>
<td>M25.261 - M25.269</td>
<td>Flail joint, knee</td>
</tr>
<tr>
<td>M25.361 - M25.369</td>
<td>Other instability, knee</td>
</tr>
<tr>
<td>M25.561 - M25.569</td>
<td>Pain in knee</td>
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<td>M25.861 - M25.869</td>
<td>Other specified joint disorders, knee [articular cartilage of knee]</td>
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<td>M89.155 - M89.158</td>
<td>Physis arrest, distal femor</td>
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<tr>
<td>M89.160 - M89.163</td>
<td>Physis arrest, proximal tibia</td>
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<tr>
<td>M92.40 - M92.52</td>
<td>Juvenile osteochondrosis of lower extremity [excluding foot]</td>
</tr>
<tr>
<td>M92.8</td>
<td>Other specified juvenile osteochondrosis [leg] [articular cartilage of knee]</td>
</tr>
<tr>
<td>M93.261 - M93.269</td>
<td>Osteochondritis dissecans knee</td>
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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).

09/20/19: Policy updated. Policy title changed from Chondrocyte Implantation of the Knee, to Focal Articular Cartilage Repair of the Knee, to include Osteochondral allografts, Osteochondral autografts and Autologous Chondrocyte Implantation, coverage and policy criteria. All procedures listed require a prior authorization for all product lines. Policy revised to reflect most current clinical evidence.

12/01/19: Medical Policy revised to include the Elite Product requiring additional prior authorization as of 1/1/2020.

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.