Medical Management Policy

Service: Autologous Chondrocyte Implantation (ACI) and Matrix-induced Autologous Chondrocyte Implant (MACI®)

PUM 250-0032-1812

Medical Policy Committee Approval 09/27/19
Effective Date 01/01/20
Prior Authorization Needed Yes

Disclaimer: This policy is for informational purposes only and does not constitute medical advice, plan authorization, an explanation of benefits, or a guarantee of payment. Benefit plans vary in coverage and some plans may or may not provide coverage for all services listed in this policy. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and federal law. Some benefit plans administered by the organization may not utilize Medical Affairs medical policy in all their coverage determinations. Contact customer services as listed on the member card for specific plan, benefit, and network status information.

Medical policies are based on constantly changing medical science and are reviewed annually and subject to change. The organization uses tools developed by third parties, such as the evidence-based clinical guidelines developed by MCG to assist in administering health benefits. This medical policy and MCG guidelines are intended to be used in conjunction with the independent professional medical judgment of a qualified health care provider. To obtain additional information about MCG, email medical.policies@wpsic.com.

Related Medical Policies:

- Cartilage Transfer Procedures: Osteoarticular Transfer System (OATS) and Mosaicplasty
- Meniscal Allograft Transplantation
- Knee Replacement Surgery
- Non-covered Services and Procedures

Description:

Autologous chondrocyte implantation (ACI) uses an individual’s own cells to repair damaged cartilage. ACI consists of two separate procedures: First, an arthroscopic biopsy is performed to remove healthy articular cartilage. The removed cartilage is then sent to a laboratory and the chondrocytes (cartilage cells) are separated out. The chondrocytes are seeded into and multiplied on a collagen membrane. The second procedure (arthrotomy) is performed to implant the membrane containing the cells into the damaged area to help repair and regenerate the articular (weight-bearing / contacting) surface.

Matrix-induced autologous chondrocyte implant (MACI®) is used as part of the ACI procedure. It consists of autologous (the individual’s own) cultured chondrocytes on a porcine collagen membrane (collagen scaffold). The surgeon trims the MACI® film / membrane to fit the area of damage and implants it to improve cartilage healing.

Indications of Coverage:

Repair of cartilage defects of the knee by autologous chondrocyte implantation (ACI) / matrix-induced autologous chondrocyte implant (MACI®) is considered medically necessary for an
individual who has given informed consent and agreed to post-operative restrictions and rehabilitation when all of the following are met:

A. The individual is between the ages of 15 and 55 years old, with body mass index (BMI) of 35 or less. Documentation of closure of growth plate is required for individuals less than 18 years old.

B. The individual experiences knee catching / locking or pain that affects ability to ambulate or complete activities of daily living.

C. The individual has completed a two month trial of physical therapy and medication management, unless contraindicated.

D. Other surgical interventions have been tried and failed or are contraindicated (e.g., osteochondral autograft, abrasion arthroplasty, microfracture, drilling).

E. There is local articular cartilage defect (caused by acute or repetitive trauma) down to, but not extending through, the subchondral bone on a load bearing surface of the patella or the trochlear, lateral or medial femoral condyle.

F. The defect does not exceed 6.0 centimeters (cm) in length, 7 millimeters (mm) in depth, and 10 square cm area.

G. Imaging demonstrates intact meniscus and no joint space narrowing.

H. Knee is aligned and stable with normal weight distribution within the joint, or procedure to ensure this is planned in combination with or prior to the chondrocyte implantation.

I. There is no arthritis of the knee present on imaging and procedure is not being performed as a treatment for degenerative arthritis.

J. The individual is not a candidate for a total knee replacement.

Limitations of Coverage:

A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.

B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, it will be denied as experimental, investigational, and unproven to affect health outcomes.

C. If used for a condition/diagnosis that is listed in the Indications of Coverage; but the criteria are not met, it will be denied as not medically necessary.

D. ACI / MACI® will be denied as experimental, investigational, and unproven to affect health outcomes in any of the following circumstances:
   1. Presence of osteochondritis dissecans (OCD) lesions
   2. History of total menisectomy
3. Hypersensitivity to porcine or bovine-derived materials
4. History of hypersensitivity to gentamycin or other aminoglycosides
5. Presence of malignancy in the area of cartilage biopsy or implantation
6. Presence of osteoarthritis, inflammatory arthritis, or inflammatory joint disease
7. When performed on an individual less than 15 years old or greater than 55 years old
8. When performed on any joint other than the knee
9. When performed on an individual with uncorrected congenital blood coagulation disorder
10. When performed on an individual who has undergone a prior knee surgery in the past 6 months (excluding the cartilage biopsy / harvest or procedure to prepare the knee for autologous chondrocyte implant)

E. The following are considered experimental, investigational, and unproven to affect health outcomes:

1. Combined autologous chondrocyte implantation and meniscal allograft
2. Combined autologous chondrocyte implantation and osteochondral autograft transfer system (OATS)
3. Combined autologous and allograft chondrocyte implantation
4. Combined meniscus reconstruction and autologous chondrocyte implantation
5. Bone marrow aspirate concentrate (BMAC) injection/treatment
6. Microfragmented adipose tissue (MFAT) injection/treatment (such as, but not limited to Lipogems®)
7. Stem cell therapy, stem cell injections
8. Platelet-rich plasma (PRP) injection/treatment
9. Platelet Lysate (PL)
10. Viscosupplementation, hyaluronic acid injections (including, but not limited to Orthovisc®, Synvisc®)
11. Juvenile cartilage allograft tissue implantation (such as, but not limited to, DeNovo NT® Natural Tissue Graft, DeNovo ET® engineered tissue graft)
12. Cryopreserved viable osteochondral allograft product (including, but not limited to Cartiform®)
13. Peripheral nerve block or ablation
14. Genicular nerve injections or genicular nerve radiofrequency ablation
15. iovera® System
16. Coolief® Cooled RF (radiofrequency)
17. Cryotherapy

Documentation Required:

- Office visit notes
**Policy Review History:**

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<tr>
<td>Implemented</td>
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<tr>
<td>Medical Policy Committee Approval</td>
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Approved by the Medical Director