

OSTEOARTHRITIS OF THE KNEE

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11/23

Date Of Origin: February 10, 2010

Status: Current

Summary of Changes

Addition:

- Autologous chondrocyte implantation (e.g., Carticel) for the repair of articular cartilage of the knee is medically necessary.
- Genicular articular embolization for osteoarthritis of the knee is experimental and investigational.

I. POLICY/CRITERIA

- A. Autologous chondrocyte implantation (e.g., Carticel) for the repair of articular cartilage of the knee is medically necessary.
- B. For arthroscopy and arthroscopically assisted surgery see Medical Policy No. 91628 – Arthroscopy and Arthroscopically Assisted Surgery – Knee, Hip, and Shoulder
- C. For arthrotomy of the knee, see Medical Policy No. 91629 – Arthrotomy – Knee and Shoulder
- D. For total joint replacement of the knee (including unicompartmental and patellofemoral), see Medical Policy No. 91630 – Total Joint Replacement – Knee, Shoulder, and Hip (Including Hip Hemiarthroplasty)
- E. The following treatments for osteoarthritis of the knee are considered experimental, investigational, or unproven:
 1. Autologous cellular implant derived from adipose tissue, autologous adipose derived regenerative cell therapy, or autologous microfragmented adipose injection (e.g., Lipogems).
 2. Bone marrow aspirate concentrate (BMAC) and platelet rich plasma (PRP) injections.
 3. Mesenchymal stem cell injections of the knee
 4. Coolief Cooled Radiofrequency Ablation for the treatment of hip and/or knee pain associated with osteoarthritis of the knee.
 5. Genicular articular embolization
 6. MAKOplasty® knee resurfacing. The MAKO® device may also be used for computer assisted navigation; as with other similar devices, this is not separately payable.

II. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

IV. DESCRIPTION

Cellular-based therapies have been proposed as a treatment option for patients with osteoarthritis (OA) of the knee who are refractory to conventional medical therapies and are ineligible for joint replacement. Biologic injections, which include mesenchymal stem cells, have been marketed for the treatment of OA. Mesenchymal stem cells (MSCs) are self-renewing and multipotent cells capable of differentiating into multiple cell types. They were originally isolated from the bone marrow stroma but have recently been identified in other tissues. Bone marrow aspirate is considered to be the most accessible source and the most common place to isolate MSCs for treatment of musculoskeletal disease. Bone marrow aspirate concentrate (BMAC) can be extracted and derived from different bones in the body. For orthopedic indications, bone marrow is generally extracted

from the iliac crest, though other sites may be utilized. BMAC is under investigation as an alternative to autologous bone grafting from the iliac crest, Centrifugation of bone marrow aspirate (e.g., Harvest SmartPrep centrifuge) to concentrate MSCs is being utilized to increase the concentration of osteoprogenitor cells. Some research has suggested that stem cell concentration may relate to overall effectiveness, hence the use of centrifugation to create BMAC. In addition to bone marrow, MSC can also be harvested from adipose tissue. Autologous cellular implant derived from adipose tissue, also known as autologous adipose derived regenerative cell therapy, or autologous microfragmented adipose injection (e.g., Lipogems) has been purposed for the treatment of degenerative joint disease or osteoarthritis. The system involves a minimally invasive procedure to harvest fat-derived stem cells then concentrate or microfragment, and finally transfer the tissue back to the patient after knee arthroscopy. Biologic injections are unproven or unsafe for current use in orthopedic conditions.

MAKOplasty (Stryker) is a robotic-assisted and computer-navigated procedure for the partial resurfacing of the knee (PKR). PKR involves the surgical removal and replacement of only the damaged surface of the knee joint with the intent of minimizing trauma to surrounding healthy bone and tissue. In a pilot study, Lonner et al (2010) compared the post-operative radiographical alignment of the tibial component with the preoperatively planned position in 31 knees in 31 consecutive patients undergoing unicompartmental knee arthroplasty (UKA) using robotic arm-assisted bone preparation and in 27 consecutive patients who underwent unilateral UKA using conventional manual instrumentation. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of Makoplasty for osteoarthritis of the knee.

Cooled radiofrequency ablation is a minimally invasive procedure that uses focused energy delivered through water-cooled electrodes to destroy tissue. The Coolief Cooled Probe and Radiofrequency Kit are indicated for creating radiofrequency lesions nervous tissue for the relief of pain, and lesions of the genicular nerves for the management of moderate-to-severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response ($\geq 50\%$ reduction in pain) to a diagnostic genicular nerve block.

Genicular or geniculate artery embolization (GAE) is a minimally invasive treatment which aims to treat OA of the knee by reducing synovial arterial hypervascularity. The procedure involves advancing a femoral catheter into the knee using x-ray imaging guidance, and an embolic agent is injected into the catheter to block the blood flow in the genicular arteries and capillaries supplying the synovium. Reducing arterial flow to the synovium reduces inflammation and nerve growth, thereby decreasing pain and possibly OA disease progression

(Padia, 2021). GAE is an outpatient interventional radiology procedure performed with the patient under moderate sedation. A consensus panel from the Society of Interventional Radiologists states that while the limited published data available suggest that GAE is effective in reducing knee pain from OA, additional safety and efficacy data to confirm their role in the algorithm for management of OA (Ahmed, 2021). In a systemic review of GAE, the authors concluded that mild-to-moderate OA treated by GAE using different embolic particles could generally be considered safe. The procedure resulted in significant and sustained pain improvement as well as better functional status in the studies reviewed. However, because of the paucity of high-quality trials (available studies lacked a control group), further investigation is needed to examine GAE's long-term outcomes, its comparative efficacy with other treatment modalities, and its role in the therapeutic approach (Torkin, 2021).

V. CODING INFORMATION

ICD-10 Codes that may apply:

- M17.0 Bilateral primary osteoarthritis of knee
- M17.10 Unilateral primary osteoarthritis, unspecified knee
- M17.11 Unilateral primary osteoarthritis, right knee
- M17.12 Unilateral primary osteoarthritis, left knee

- M17.2 Bilateral post-traumatic osteoarthritis of knee
- M17.30 Unilateral post-traumatic osteoarthritis, unspecified knee
- M17.31 Unilateral post-traumatic osteoarthritis, right knee
- M17.32 Unilateral post-traumatic osteoarthritis, left knee

- M17.4 Other bilateral secondary osteoarthritis of knee
- M17.5 Other unilateral secondary osteoarthritis of knee
- M17.9 Osteoarthritis of knee, unspecified

CPT/HCPCS Codes

- 27412 Autologous chondrocyte implantation, knee
- J7330 Autologous cultured chondrocytes, implant

CPT/HCPCS Codes Not Covered for the indications in the policy:

- 0054T Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure)
- 0055T Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (List separately in addition to code for primary procedure)
- 0232T Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed

- 0481T Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed
- 0565T Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation
- 0566T Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral
- 20999 Unlisted procedure, musculoskeletal system, general
- 27599 Unlisted procedure, femur or knee
- 27438 Arthroplasty, patella; with prosthesis
- 27442 Arthroplasty, femoral condyles or tibial plateau(s), knee;
- 37242 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)
- 38206 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
- 38232 Bone marrow harvesting for transplantation; autologous
- 38241 Hematopoietic progenitor cell (HPC); autologous transplantation
- 64454 Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed nNot covered if billed for Coolief for any product)
- 64624 Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed (not covered if billed for Coolief for any product)

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