

OSTEOARTHRITIS OF THE KNEE

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Review Dates: 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16,
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Date Of Origin: February 10, 2010

Status: Current

Summary of Changes

Clarifications:

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Deletions:

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Additions:

- Pg. 1, Section I, 3, criteria updated to reflect bone marrow aspirate concentrate (BMAC) and platelet rich plasma (PRP) injections are considered experimental, investigational, or unproven, and therefore, are not covered.

I. POLICY/CRITERIA

The following treatments for osteoarthritis of the knee are considered experimental, investigational, or unproven, and therefore, are not covered:

1. The use of patellofemoral replacement (PFR) for isolated patellofemoral osteoarthritis
2. Mesenchymal stem cell injections of the knee
3. Bone marrow aspirate concentrate (BMAC) and platelet rich plasma (PRP) injections
4. MAKOpasty[®] knee resurfacing.

The MAKOpasty[®] 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); 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

Patellofemoral replacement (PFR) is the implantation of prostheses that replace the surfaces of the patella and femur at the knee joint. Potential candidates for PFR replacement have severe pain from isolated patellofemoral osteoarthritis (PFOA) that does not respond to nonsurgical or surgical therapies, and in whom there is no malalignment of the kneecap.

Isolated patellofemoral osteoarthritis, involving only the junction between the patella and the femur, affects 5% to 10% of patients who present with knee pain. The disease is diagnosed through a history of patellofemoral pain and stiffness, and demonstration of damage to the articular surface in the presence of normal tibiofemoral articulation on plain radiographs, computed tomography, magnetic resonance imaging, or arthroscopy.

Review of available evidence on the efficacy and safety of PFR for isolated patellofemoral osteoarthritis show benefits in some patients, however all of the available studies are limited by small populations and the lack of controls, and in some studies, inadequate follow-up times and an unacceptable loss of patients to follow-up can bias the results. In addition, there are no randomized controlled studies comparing PFR with total knee replacement or with other therapies for patellofemoral osteoarthritis including other surgeries. Additional information from well-designed studies is needed to determine the effects of factors such as age, gender, preoperative diagnosis, device/implant design (e.g., off-the-shelf and customized implants), and anatomical variations, etc., on the outcomes of PFR.

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.

MAKOplasty[®]: Although there was a moderate amount of literature addressing robotic-assisted and computer-navigated orthopedic procedures for the knee, only 8 abstracts were found that specifically mentioned Mako surgery, Makoplasty, or RIO System components for knee procedures. The retrospective clinical studies evaluated the risk for overcorrection and the impact of residual osteoarthritis (patellofemoral and lateral compartment) on medial unicompartmental knee replacement. The case report described clinical experience in a patient with combined medial compartment osteoarthritis and a subchondral defect of the medial femoral condyle. Conclusions: 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. (Hayes February 2016)

American Academy of Orthopaedic Surgeons: MAKO Surgical's RIO[®] Robotic Arm Interactive Orthopedic System ([A](#)) is now available for use in MAKOplasty[®] total hip arthroplasty (THA) procedures. The total hip replacement application is designed to support the surgeon's ability to more accurately align and position the implants relative to the needs of a patient. MAKOplasty THA provides the surgeon with a preoperative 3-dimensional (3-D) reconstruction of the patient's hip, which is used to develop the patient-specific surgical plan. The robotic arm then assists the surgeon during the procedure to accurately prepare the joint and optimally place hip implants. <http://www.aaos.org/search/?srchtext=makoplasty>. No AAOS statement found for use in knees (Accessed December 15, 2016)

V. CODING INFORMATION

ICD-10 Codes that may apply:

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

- M17.2 Bilateral post-traumatic osteoarthritis of 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 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

- 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;

- 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

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