## Summary of Changes

### Clarifications:
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### Deletions:
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### Additions:
- Pg. 1, Section I, 3, criteria updated to reflect MAKOplasty® knee resurfacing is considered experimental, investigational, or unproven, and therefore is 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. MAKOplasty® knee resurfacing.

The MAKOplasty® 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
- [x] 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
VI. REFERENCES

1. Hayes Technology Brief – Patellofemoral replace for Osteoarthritis October 13, 2009


40. Hayes, Inc. MAKOplasty (MAKO Surgical Corporation) for Knee Arthroplasty, February 4, 2016
41. American Academy/Association or Orthopaedic Surgeons @ http://www.aaos.org/search/?srchtext=makoplasty (Accessed December 15, 2016)
43. Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedures of the Appendicular System, Anthem Blue Cross @