Guidelines for Medical Necessity Determination for Knee Arthroplasty

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for knee arthroplasty. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 433.000 (physician services), and 450.000 (administrative and billing regulations), and Subchapter 6 of the Physician Manual for information about coverage, limitations, service conditions, and prior authorization requirements. Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP) or managed care organization (MCO), should refer to the ACPP's or MCO's medical policies for covered services.

MassHealth requires prior authorization for knee arthroplasty and reviews prior authorization requests on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

1 SECTION I. GENERAL INFORMATION

Knee arthroplasty is an orthopedic surgical procedure designed to address symptoms of pain or decreased function in a knee damaged by arthritis or trauma. Arthroplasty is generally considered when non-operative medical treatment no longer effectively manages pain in or reduced function of the joint. During an arthroplasty, the articular surface of the joint may be replaced, remodeled, or realigned using a number of different procedures. The goal of treatment is to improve joint stiffness or mobility and relieve pain.

MassHealth considers approval for coverage of knee arthroplasty on an individual, case-by-case basis, in accordance with 130 CMR 450.204.

2 SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

Arthroplasty describes the surgical replacement or reconstruction of a joint with implanted devices when the joint has been damaged by an arthritic or traumatic process. MassHealth bases its determination of medical necessity for knee arthroplasty on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of the procedure including post-operative recovery. This medical necessity guideline outlines the clinical indications for three types of knee arthroplasty procedures: total knee arthroplasty, partial/unicompartmental knee arthroplasty, and revision knee arthroplasty. The criteria for each of the three types of knee arthroplasty include, but are not limited to, the following.

1. **TOTAL KNEE ARTHROPLASTY (TKA)** describes the surgical reconstruction or replacement of all articular joint surfaces of the entire knee joint which results from a malformed or degenerated knee joint or replacement due to failure or complications of previous knee arthroplasty. TKA may be medically necessary when ALL of the following criteria (a through e) are met:

    a. Extensive disease or damage due to rheumatoid arthritis, fracture, or avascular necrosis confirmed by imaging (radiographs, MRI or other advanced imaging);

    b. Both of the following criteria (1 and 2) are met:

        1. Pain that is persistent and severe, or member has documented loss of function that has been present for at least 6 months resulting in a diminished quality of life;

        2. Three months or more of non-operative care including at least two or more from the list in Appendix A has failed to improve symptoms described in 1.b.1 above;

    c. Physical exam findings demonstrate one of the following (1 or 2):

        1) Tenderness, swelling, effusion, and limited range of motion (decreased from uninvolved side or as compared to a normal joint);

        2) Flexion contracture, palpable or audible crepitus, instability or angular deformity;

    d. MRI and weight-bearing radiographic findings show evidence of bicompartmental or tricompartmental advanced arthritic changes described as Kellgren-Lawrence stage III or stage IV degeneration (see Appendix B);

    e. Requests for simultaneous bilateral total knee replacements for members with chronic, painless effusion and extensive radiographic arthritis will be reviewed on a case-by-case basis.

2. **UNICOMPARTMENTAL KNEE ARTHROPLASTY (UKA)/PARTIAL KNEE REPLACEMENT (PKA)** - also called partial, hemi- or unicondylar knee, arthroplasty involves reconstruction of either the medial or lateral weight bearing compartments of the knee and/or patellofemoral joint. UKA/PKA may be considered medically necessary as an alternative to Total Knee Arthroplasty (TKA) for patients with documented unicompartmental disease when ALL of the following criteria (a through g) are met:

    a. Pain is present for at least 6 months and localized to the medial or lateral compartments;

    b. Six months or more of non-operative care including at least two or more from the list in Appendix A has failed to improve symptoms;

    c. Joint measurements on physical examination using a goniometer include total arc of motion > 90 degrees; contracture < 5-10 degrees, and angular deformity < 10 passively correctable to neutral;

    d. Normal ACL or stable reconstructed ACL per physical exam;

    e. Age > 50 years;*

    f. MRI and weight-bearing radiographic findings demonstrate only unicompartmental disease (with or without patellofemoral involvement) with evidence of degeneration equal to Kellgren-Lawrence stage III or IV (see Appendix B);

g. BMI < 40.*

** For members younger than age 50 years, and for member with BMI > 40, documentation must confirm the member has completed at least 24 weeks of unsuccessful non-operative treatment including the use of assistive device, therapeutic injections, and weight reduction program. See Appendix A*

3. **REVISION ARTHROPLASTY/REVISION TOTAL KNEE ARTHROPLASTY (TKA)** is a surgical reconstruction of the knee due to failure or complication of a previous arthroplasty. Criteria for revision arthroplasty/TKA may be considered medically necessary when one of the two following criteria (a or b) are present.

   a. The member has had a previous UKA/PKA or TKA joint arthroplasty, infection has been ruled out by synovial fluid aspiration/biopsy (cell count and/or culture) and the member is off antibiotics;

   b. ALL of the following criteria (1, 2 and 3) are met:

      1. Symptomatic UKA/PKA or TKA as evidenced by persistent, severe disabling pain and loss of function;

      2. Any of the following upon physical exam: tenderness to palpation objectively attributable to the implant, swelling, effusion, pain on weight-bearing or motion, instability on stress-testing, abnormal or limited motion compared to usual function, palpable or audible crepitus associated with reproducible pain;

      3. Aseptic loosening, osteolysis confirmed on radiographic or advanced imaging (nuclear medicine bone scan, CT scan, or MRI).

B. NONCOVERAGE

MassHealth does not consider knee arthroplasty to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following:

1. The following three procedures are considered investigational or experimental and are not covered:

   a. Procedures utilizing computer-navigated or patient-specific or gender-specific instrumentation;

   b. Bicompartmental arthroplasty;

   c. Robot-assisted TKA (Makoplasty);

2. Absolute contraindication to total knee replacement, unicompartmental knee arthroplasty/partial knee replacement, and revision arthroplasty includes active infection either systemic or located locally or remote to the knee;

3. Relative contraindications to TKA, include any of the following conditions:

   a. Prior infection at site (unless aspiration with cultures and serology, CBC with differential, ESR, and CRP, demonstrate no infection). If prior infection at site, tissue biopsies should be sent intra-operatively to exclude latent/dormant infection;

   b. Morbid obesity (BMI > 40);

   c. Articular injection within the last 3 months;

4. Relative contraindications to TKA or revision arthroplasty/revision TKA include any of the following:

    a. Deficiency of the extensor mechanism;

    b. Neuropathic joint;

    c. Unstable or poorly controlled comorbidities;

    d. Severe peripheral vascular disease;

    e. Compromised soft-tissue envelope (revision may be performed in conjunction with plastic surgical consultation for soft tissue coverage via pedicle flaps or other acceptable procedure);

5. Absolute contraindications to UKA/PKA include any of the following:

    a. Inflammatory arthritis including significant arthritic involvement of other knee compartments;

    b. Angular deformity or contracture greater than indicated range in II.A.2.c.;

    c. Ligamentous instability (at least anterior cruciate ligament);

    d. Poor bone quality or significant osteoporosis or osteopenia;

    e. Meniscectomy of the opposite compartment;

    f. Stiffness greater than indicated range of motion II.A.2.c.

SECTION III: SUBMITTING CLINICAL DOCUMENTATION

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Requests for prior authorization for knee arthroplasty must be submitted by an orthopedic surgeon that is a MassHealth provider and accompanied by clinical documentation that supports the medical necessity for this procedure.

A. Documentation of medical necessity must include all of the following:

1. The primary diagnosis name(s) and the ICD-CM code(s) for the condition requiring arthroplasty;
2. The secondary diagnosis name(s) and ICD-CM code(s) pertinent to any co-morbid conditions, if present;
3. A description of the specific arthroplastic procedure and appropriate CPT code(s) for the procedure being requested;
4. The most recent medical evaluation, including a summary of the medical history and the most recent physical exam with emphasis on the orthopedic knee examination and testing specific to the patient's condition;
5. Results of any radiology studies (e.g., routine x-rays, MRI, CT, etc.) and other tests that may have been previously performed and are relevant to the condition for which arthroplasty is being requested;
6. A summary of the non-operative, conservative treatment(s) that have been tried and have been unsuccessful in managing the patient's condition;
7. Any risk factors and co-morbid conditions;
8. Other pertinent information that MassHealth may request.

B. Clinical information must be submitted by an orthopedic surgeon. *Providers are strongly encouraged to submit requests electronically*. Providers must submit all information pertinent to the diagnosis using the Provider Online Service Center (POSC) or by completing a MassHealth Prior Authorization Request form (using the PA-1 paper form found at www.mass.gov/masshealth) and attaching pertinent documentation. The PA-1 form and documentation should be mailed to the address on the back of the form. Questions regarding POSC access should be directed to the MassHealth Customer Service Center at 1-800-841-2900.

Appendices

APPENDIX A: CONSERVATIVE, NON-OPERATIVE TREATMENTS FOR KNEE CONDITIONS

1. Modifications in activity including
    a. Rest or activity modification or limitation
    b. Bracing/orthosis or walking aids
    c. Protected weight bearing
    d. Weight optimization
2. Physical therapy modalities
    a. Ice/heat
    b. Exercises to strengthen and improve mobility in formal physical therapy sessions
    c. Supervised home exercise to strengthen and improve mobility
3. Medication
    a. Oral/topical NSAIDS or other analgesics
    b. Injections such as cortisone

APPENDIX B: KELLGREN-LAWRENCE (KL) GRADING SYSTEM

Grade 0: No radiographic features of osteoarthritis

Grade I: Possible joint space narrowing and osteophyte formation

Grade II: Definite osteophyte formation with possible joint space narrowing

Grade III: Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour

Grade IV: Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour

Select References

1. AHRQ National Guideline Clearinghouse. American Academy of Orthopaedic Surgeons clinical practice guideline on surgical management of osteoarthritis of the knee. *Am Acad Orthop Surg.* 2015.

2. Bistolfi A, Federico AM, Carnino I, Gaido C, Da Rold I, Magistroni E, Actis MV, Aprato A, Massazza G. Rehabilitation and Physical Therapy before and after Total Knee Arthroplasty: A Literature Review and Unanswered Questions. *Int J Phys Med Rehabil* 4:356. doi: 10.4172/2329-9096.1000356 https://www.omicsonline.org/open-access/rehabilitation-and-physical-therapy-before-and-after-total-knee-arthroplasty-aliterature-review-and-unanswered-questions-2329-9096-1000356.php?aid=77334

3. Cram P, Lu X, Kates SL, Singh JA, Li Y, Wolf BR. Total knee arthroplasty volume, utilization, and outcomes among Medicare beneficiaries, 1991-2010. *JAMA*. 2012 Sep 26;308(12):1227-36.

4. Hochberg MC, Altman RD, April KT, Benkhalti M, Guyatt G, McGowan J, Towheed T, Welch V, Wells G, Tugwell P. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res (Hoboken)*. 2012 Apr;64(4):465-74.

5. Ibrahim MS, Alazzawi S, Nizam I, Haddad FS. An evidence-based review of enhanced recovery interventions in knee replacement surgery. *Ann R Coll Surg Engl.* 2013 Sep; 95(6): 386–389.

6. Newman J, Pydisetty RV, Ackroyd C. Unicompartmental or total knee replacement: the 15-year results of a prospective randomised controlled trial. *J Bone Joint Surg Br* 2009; 91:52.

7. Wallis JA, Taylor NF. Pre-operative interventions (non-surgical and non-pharmacological) for patients with hip or knee osteoarthritis awaiting joint replacement surgery – a systematic review and meta-analysis. *Osteoarthritis and Cartilage* 2011:19(12):1381-1395. https://www.sciencedirect.com/science/article/pii/S1063458411002603

These Guidelines are based on review of the medical literature and current practice in arthroplasty. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, contact your health-care provider for guidance or explanation.

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Approved by _____
Jill D. Morrow-Gorton, MD, MBA
Acting Chief Medical Officer, MassHealth