Knee Joint Replacements

Policy Number:	**M20210611026**
Effective Date:	**9/1/2021**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☐ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☒Child Health Plus; ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth the medical necessity criteria for **total knee arthroplasty (TKA).**

Policy:

Commercial and Self-Funded:
General Requirements (all procedures below):

When any procedure is indicated for advanced joint disease, the following should be documented in the medical record:

1. Arthritis of the knee supported by X-ray or MRI. The X-ray or MRI should demonstrate one of the following:
    - subchondral cysts,
    - subchondral sclerosis,
    - periarticular osteophytes,
    - joint subluxation,
    - joint space narrowing,
    - avascular necrosis, or
    - bone on bone articulations

2. The extent to which pain or functional disability interferes with activities of daily life (ADL) (functional disability), increases with activity, or increases with weight bearing. ADLs include, but are not limited to, dressing, feeding, toileting, grooming, physical ambulation (including balance/risk of falls), and bathing.

3. Once imaging demonstrates need for replacement, and the patient has met the policy criteria, and the patients overall clinical condition has not changed, and is considered appropriate for proceeding with surgery, the procedure does not have to be performed within a specific amount of time. If the request is submitted 6 months after the last clinical visit, an attestation by the requesting surgeon that the patient does not need repeat imaging and clinical status has not changed must be provided.

4. Documentation reflected in the member's medical records required of non-surgical medical management measures by the requesting provider, ordered by them or other health professionals during the patient's course of treatment for a period of 3 months for this condition(s).
    - Documentation should establish a history of a reasonable attempt at conservative therapy as appropriate for the patient in their current episode of care.
    - Documentation to include the start date of each therapy and the concluding date of therapy with the results of therapy included as outlined below.
    - The documentation should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including 2 or more of the following:
        a. prescription or non-prescription anti-inflammatory medications and/or analgesics; outcomes of medication therapy, including medication name, dosage and frequency documented in the medical record by ordering provider including the start and end dates of medication therapies and/or
        b. flexibility and muscle strengthening exercises; the description of flexibility and muscle strengthening exercises as ordered by the provider and outcomes of flexibility and muscle strengthening exercises is required to be documented in the medical record and/or
        c. supervised physical therapy; Complete therapy progress note documentation submission by the therapy provider required and/or
        d. assistive device use; the description of an assistive device as ordered by the provider and outcomes its use is required to be documented in the medical record and/or
        e. reasonable activity modifications; the description of activity modification as ordered by the provider and outcomes of modification is required to be documented in the medical record and/or
        f. weight reduction as appropriate; start and end date of weight reduction and results of any reduction is required to be documented in the medical record and/or

g. therapeutic injections into the joint as appropriate; procedure report submission required, and outcomes of therapy documented in the medical record.

Non-surgical medical management may be inappropriate, ineffective, or counterproductive when one or more of the following is present:

a. bone on bone articulation; and/or
b. severe deformity; and/or
c. severe pain (particularly at rest) and significant disabling interference with activities of daily living (ADL).

5. For patients with BMI > 40, there must be failure of at least six (6) months of provider-directed non-surgical management.
    a. Provider-directed non-surgical management may be inappropriate. The medical record must clearly document why provider-directed non-surgical management is not appropriate. **Note:** The duration of provider-directed non-surgical management allows for preoperative optimization of reasonably modifiable medical and behavioral health comorbidities.

6. For patients with significant conditions or co-morbidities, such as coronary artery disease or obstructive pulmonary disease, the risk/benefit of the TKA should be appropriately addressed in the medical record.

7. Adherence to a tobacco-cessation program resulting in abstinence from tobacco for at least 6 weeks prior to surgery is recommended. In smokers, medical documentation must state the provider reviewed the benefits of smoking cessation prior to elective surgery as it appears to improve a number of outcomes such as wound healing and postoperative pulmonary recovery.

8. For members with diabetes every effort should be made to ensure it is well controlled. Members with poor control as evidenced by an elevated HbA1c levels (> 8.5%), every effort should be made to optimize glycemic levels prior to elective surgery. If optimization is not possible, there is documentation that the surgeon has reviewed the increased risks associated with joint replacement procedures with the member prior to the procedure.

9. Medical record documentation for TKA indications other than advanced joint disease outlined above should include the following, when indicated:
    a. Supporting evidence (e.g., pathology reports and referral from an Oncologist for a malignancy of the joint or X-ray of a fracture).
    b. The extent to which pain or functional disability interferes with ADLs (functional disability), increases with initiation of activities or weight bearing.
    c. For patients with significant conditions or co-morbidities, such as coronary artery disease or obstructive pulmonary disease, the risk/benefit of the TKA should be appropriately addressed in the medical record.

<u>Partial Knee Replacement</u>

Partial knee replacement (medial, lateral, or patellofemoral unicompartmental) is considered medically necessary when ALL of the following criteria have been met:

a. Function-limiting pain at short distances (e.g., walking less than ¼ mile, limiting activity to two city blocks, the equivalent to walking the length of a shopping mall) for at least three (3) months duration

b. Loss of knee function which interferes with the ability to carry out age-appropriate activities of daily living and/or demands of employment
c. Radiographic or arthroscopic findings of EITHER of the following:
    i. Severe unicompartmental (medial, lateral, or patellofemoral) degenerative arthritis evidenced by EITHER of the following:
        - Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour (i.e., Kellgren-Lawrence Grade IV radiographic findings)
        - Exposed subchondral bone (i.e., **Outerbridge Classification** Grade IV arthroscopy findings)
    ii. Avascular necrosis (AVN) of the femoral condyles and/or proximal tibia
d. Intact, stable ligaments, in particular the anterior cruciate ligament
e. Knee arc of motion (full extension to full flexion) greater than 90º
f. Failure of at least three (3) months of provider-directed non-surgical management. Clear documentation must be provided if the medical provider-directed non-surgical management is not appropriate.

Partial knee replacement (medial, lateral, or patellofemoral unicompartmental) is considered not medically necessary for any other indication or condition, when ANY of the following criteria is present:

a. When unicompartmental replacement is to be performed of the medial or lateral compartment:
    i. Grade IV patellofemoral joint arthritis involving the lateral patella facet and/or lateral trochlea as evidenced by EITHER of the following:
        - Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour (i.e., Kellgren-Lawrence Grade IV radiographic findings)
        - Exposed subchondral bone (i.e., Outerbridge Classification Grade IV arthroscopy findings)
b. When unicompartmental replacement is to be performed of the patellofemoral compartment:
    i. Grade III or IV medial or lateral compartment degenerative changes as evidenced by ANY of the following:
        - Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis, and possible deformity of bone contour (i.e., Kellgren-Lawrence Grade III radiographic findings)
        - Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour (i.e., Kellgren-Lawrence Grade IV radiographic findings)
            - Fragmentation and fissuring greater than one square centimeter (1 cm2) (i.e., Outerbridge Classification Grade III arthroscopy findings)
            - Exposed subchondral bone (i.e., Outerbridge Classification Grade IV arthroscopy findings)
c. Tibial or femoral shaft deformity
d. Radiographic evidence of medial or lateral subluxation
e. Flexion contracture greater than 15º
f. Varus deformity greater than 15º
g. Valgus deformity greater than 20º
h. Inflammatory arthropathy

i. Active local or systemic infection
j. Osseous abnormalities that cannot be optimally managed prior to surgery which would increase the likelihood of a poor surgical outcome (i.e., inadequate bone stock to support the implant)
k. Severe lack of collateral ligament integrity leading to joint instability
l. Charcot joint
m. One or more medical condition(s) that is (are) not optimized preoperatively that would significantly increase the risk of morbidity (e.g., cardiac, pulmonary, liver, genitourinary, or metabolic disease; hypertension; abnormal serum electrolyte levels)
Note: It is incumbent on the surgeon to optimize reasonably modifiable medical comorbidities preoperatively.
n. Vascular insufficiency, significant muscular atrophy of the leg, or neuromuscular disease severe enough to compromise implant stability or post-operative recovery
o. Severe immunocompromised state

Total Knee Arthroplasty (TKA)

Total Knee Replacement is considered medically necessary when ALL of the following criteria have been met:

a. Function-limiting pain at short distances (e.g., walking less than ¼ mile, limiting activity to two city blocks, the equivalent to walking the length of a shopping mall) for at least three (3) months duration.
b. Loss of knee function which interferes with the ability to carry out age-appropriate activities of daily living and/or demands of employment
c. Radiographic or arthroscopic findings of EITHER of the following:
    i. Severe unicompartmental (medial, lateral, or patellofemoral), bicompartmental, or tricompartmental degenerative arthritis evidenced by EITHER of the following:
        - Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour (i.e., Kellgren-Lawrence Grade IV radiographic findings)
        - Exposed subchondral bone (i.e., Outerbridge Classification Grade IV arthroscopy findings)
    ii. Avascular necrosis (AVN) of the femoral condyles and/or proximal tibia

Total Knee Arthroplasty is considered medically necessary for a fracture of the distal femur when conservative management or surgical fixation is not considered a reasonable option.

Total Knee Arthroplasty is considered not medically necessary for any other indication or condition, including when ANY of the following criteria is present:

a. Active local or systemic infection
b. Osseous abnormalities that cannot be optimally managed and which would increase the likelihood of a poor surgical outcome (i.e., inadequate bone stock to support the implant)
c. Joint instability due to a lack of collateral ligament integrity not amenable to surgical correction (e.g., specialized implant, constrained implant, or a hinge implant)
d. Greater than 30 degrees of fixed varus or valgus deformity not amenable to surgical correction
e. One or more medical condition(s) that is (are) not optimized preoperatively that would significantly increase the risk of morbidity (e.g., cardiac, pulmonary, liver, genitourinary, or metabolic disease; hypertension; abnormal serum electrolyte levels)

Note: It is incumbent on the surgeon to optimize reasonably modifiable medical comorbidities preoperatively.

f. Vascular insufficiency, significant muscular atrophy of the leg, or neuromuscular disease severe enough to compromise implant stability or post-operative recovery
g. Severe immunocompromised state
h. Patients on dialysis who are on a renal transplant list

Replacement/Revision Knee Arthroplasty

Replacement/Revision knee arthroplasty is considered reasonable and necessary for individuals with one or more of the following:

a. Loosening of one or more component; or
b. Fracture or mechanical failure of one or more components, or
c. Infection, or
d. Periprosthetic fracture of distal femur, proximal tibia or patella, or
e. Progressive or substantial periprosthetic bone loss, or
f. Bearing surface wear with symptomatic synovitis, or
g. Implant or knee misalignment, or
h. Knee stiffness/arthrofibrosis, or
i. Tibiofemoral instability, or
j. Extensor mechanism instability

TKA or total knee revision is not considered reasonable or necessary when none of the criteria above are met.

Medicare Advantage:

There is currently a Local Coverage Determination (LCD) and a Local Coverage Article (LCA) for total joint arthroplasty. Please refer to the links listed in the Reference section for Medicare Advantage members.

MediSource, MediSource Connect, Child Health Plus and Essential Plan

MediSource, MediSource Connect, Child Health Plus and Essential Plan cover total knee replacements, replacements and revisions utilizing the criteria above.

Background:

Knee joint replacement, also known as Total knee arthroplasty (TKA), is indicated for patients with significant loss or erosion of cartilage to bone accompanied by pain and limited range of motion (ROM), in patients who have had an inadequate response to conservative measures. TKA consists of resection of the diseased articular surfaces of the knee, followed by resurfacing with metal and polyethylene prosthetic components [5]. For the properly selected patient, the procedure results in significant pain relief, as well as improved function and quality of life. In spite of the potential benefits of TKA, TKA is usually performed on an elective basis and should only be considered after exhaustion of appropriate nonsurgical therapies and extensive discussion of the risks, benefits, and alternatives.

According to UpToDate ”osteoarthritis is the most common type of arthritis in adults and can result in degenerative changes in the knee joint. Over 95 percent of TKAs in the United States are performed for osteoarthritis . In patients with osteoarthritis, TKA is indicated for the relief of severe knee pain that is refractory to nonoperative treatments. Before proceeding to TKA, a multifaceted regimen of nonoperative treatment should be tried. Nonsurgical treatments offer significant benefit with lower risk. The efficacy of these nonsurgical interventions, even with advanced osteoarthritis, has been supported

in clinical trials and are appropriate, particularly in patients looking to avoid or postpone surgical intervention or for patients not fit for surgery."

Pre-Authorization Required? Yes ☒ No ☐

Preauthorization is required for all lines of business except Medicare for this service.

Definitions

Outerbridge Classification is a classification system describing varying severity of cartilage lesions by direct visualization assigning a grade of 0 through IV to the chondral area of interest . Grade 0 signifies normal cartilage. Grade I chondral lesions are characterized by softening and swelling, which often require tactile feedback with a probe or other instrument to assess. A Grade II lesion describes a partial-thickness defect with fissures that do not exceed 0.5 inches in diameter or reach subchondral bone. Grade III is fissuring of the cartilage with a diameter > 0.5 inches with an area reaching subchondral bone. The most severe is Grade IV, which includes erosion of the articular cartilage that exposes subchondral bone.

Kellgren-Lawrence is a classification scale describing varying severity of osteoarthritis. Grade 0 (none): definite absence of x-ray changes of osteoarthritis; Grade 1 (doubtful): doubtful joint space narrowing and possible osteophytic lipping; Grade 2 (minimal): definite osteophytes and possible joint space narrowing; Grade 3 (moderate): moderate multiple osteophytes, definite narrowing of joint space and some sclerosis and possible deformity of bone ends; Grade 4 (severe): large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone ends.

Total knee arthroplasty (TKA) consists of resection of the diseased articular surfaces of the knee, followed by resurfacing typically with metal and polyethylene prosthetic components.

References

Related Policies, Processes and Other Documents
N/A

Non-Regulatory references
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Regulatory References

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This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
11/1/2025	Health Care Services	Reviewed
8/1/2024	Health Care Services	Revised
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8/1/2022	Health Care Services	Revised
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