BlueCross BlueShield of Alabama

**Name of Policy:**
# Knee Arthroplasty

Policy #: 705
Category: Surgical
Latest Review Date: March 2018
Policy Grade: A

## Background/Definitions:

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

## Description of Procedure or Service:

Total knee arthroplasty (TKA) is one of the five most frequently performed inpatient procedures in the United States. In 2010, an estimated 693,400 total knee arthroplasties were performed on individuals aged 45 or older. This number is expected to grow as the population ages with a projected increase to 3.48 million procedures per year by 2030. The vast majority of cases of TKAs are due to degenerative joint disease; osteoarthritis (OA) is the most common form of this condition.

Osteoarthritis

Approximately 14% of U.S. adults will be affected by OA during their lifetime. For individuals over the age of 65 years, the rate of those affected increases to 33.6%. OA is a progressive joint disease that ultimately damages the entire joint, and although disease progression cannot be reversed, conservative treatment can frequently slow or mitigate the progression of the disease. Conservative treatments (non-surgical medical management) may consist of activity modification, anti-inflammatory medications or analgesics, assistive device use, exercise programs, injections, knee braces, orthotics, supervised physical therapy and weight loss. If these measures fail, then TKA may be considered an appropriate option. Thus knee OA should initially be treated conservatively, but surgery may be considered if symptoms persist.

Surgical treatments for knee OA include arthroscopy, osteotomy, and knee arthroplasty; determining which of these procedures is most appropriate will depend on several factors, including the location and severity of OA damage, patient characteristics, and risk factors. The main indication for total knee arthroplasty is for the relief of pain associated with arthritis of the knee which affects 2 or 3 compartments in patients who have failed the aforementioned nonsurgical, conservative treatments. Modern TKA consists of resection of the diseased articular surfaces of the knee, followed by resurfacing with metal and polyethylene prosthetic components. The lifespan of the prosthetic joint is limited and based on variables including patient age, severity of knee disease, comorbidities, obesity, as well as prosthetic and surgical factors.

Post-traumatic Arthritis

Post-traumatic arthritis (PTA) is a condition triggered by an acute joint trauma that can lead to osteoarthritis or chronic inflammatory arthropathies. This condition can occur at any age, in any joints and may develop from any kind of acute physical trauma, such as sports, vehicle accident, blunt trauma, fall or etc. Although any joint in the body may be involved, PTA is often more notable in weight-bearing joints. A single trauma may sometimes be sufficient to induce arthropathy, however, repeated injuries and excess body weight are known to increase the risk for post-traumatic arthritis. Reconstruction options for symptomatic posttraumatic knee arthritis include osteotomy, arthrodesis, and arthroplasty. Surgical challenges include the presence of extensive (often broken) hardware, scarring, stiffness, bony defects, compromised soft tissues, and malalignment. Patient age and activity and the anatomic location and extent of damage to the articular surface must be taken into account when determining the surgical treatment plan. For younger patients, osteotomy, allograft transplantation, or arthrodesis of the knee is considered, whereas older, low-demand patients are usually treated with arthroplasty.

Rheumatoid Arthritis

Rheumatoid arthritis is a chronic inflammatory and progressive disease characterized by symmetrical joint involvement, which causes pain, swelling, stiffness, and loss of function in the joints. If left untreated, it may lead to joint destruction and progressive disability. Rheumatoid arthritis affects 2.1 million Americans usually striking people between the ages of 20 and 60, and people in their mid to late fifties are especially vulnerable. Rheumatoid arthritis is three times more common in women than in men. The traditional nonsurgical approach consists of non-steroidal anti-inflammatory drugs (NSAIDs) to reduce pain, swelling, and inflammation, plus a disease-modifying antirheumatic drug (DMARD) such as methotrexate to slow the course of the disease and prevent joint and cartilage destruction, physical therapy, or assistive devices. Total knee arthroplasty is considered for individuals who have exhausted other conservative treatment options.

For the properly selected patient, TKA could result in significant pain relief, as well as improved function and quality of life. Despite the potential benefits and successful outcomes, TKA is an elective procedure and should only be considered after extensive discussion of the risks, benefits, and alternatives.

Unicompartmental Knee Replacement

For a small percentage of patients with advanced osteoarthritis limited to a single compartment, a unicompartmental or partial knee replacement may be a treatment option. In this type of surgery, only the damaged knee compartment is replaced with metal and plastic- preserving healthy cartilage, ligaments and bone. Unicompartmental knee replacements are subject to the same criteria requirements as listed below for TKAs**.**

This policy does not discuss the interpositional unicondylar spacer (e.g., UniSpacer). Refer to medical policy, *#125- Unicondylar Interpositional Spacer as a Treatment of Unicompartmental Arthritis of the Knee* for information regarding this technology.

## Policy:

**Effective for dates of service to be determined after draft period:**

**These criteria only apply to patients aged 18 years and older.**

**Medical clearance is required for patients with moderate to severe co-morbid conditions (e.g., cardiac disease, pulmonary disease, or diabetes) for assessment of pre-surgical risk and/or patient's ability for compliance with postoperative rehabilitation activities.**

**Knee arthroplasty (total or unicompartmental)** meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the following indications in the absence of an active infection (local or systemic):

1. Primary or metastatic tumor with limb salvage surgery
2. Extensive disease or damage confirmed by imaging **AND** documented pain and loss of function due to **ONE** of the following:
    a. Avascular necrosis

b. Symptomatic malunion or nonunion of articular fracture (including distal femur or proximal tibia fracture)
c. Bone-on-bone articulation

3. Persistent, symptomatic degenerative joint disease (DJD), post-traumatic arthritis or rheumatoid arthritis(all confirmed by imaging), when **ALL** of the following conditions are met:

**Pain**

a. Documentation of at least **TWO** of the following:
    i. Pain that interferes with ADLs
    ii. Increased pain with activity
    iii. Increased pain with weight bearing

**AND**

**Motion**

b. Documentation of at least **TWO** of the following findings on physical examination:
    i. Limited range of motion
    ii. Crepitus
    iii. Joint effusion or swelling

**AND**

**Imaging**

c. Radiographic evidence of severe arthritis as evidenced by the presence of at least **TWO** of the following:
    i. Joint space narrowing
    ii. Subchondral cysts
    iii. Subchondral sclerosis
    iv. Periarticular osteophytes
    v. Joint subluxation
    vi. Marginal erosion (For RA only)

**AND**

**Therapy**

d. Documentation of 3 months of unsuccessful conservative therapy including at least **ONE** of the following:
    i. prescription strength analgesics/anti-inflammatory medications
    ii. prescribed topical agents
    iii. activity modification
    iv. supervised therapeutic exercise
    v. assistive devices
    vi. bracing

vii. therapeutic knee injections (as appropriate)

**Revision or replacement of arthroplasty meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for **ANY** of the following indications when accompanied by pain and functional disability:

1. Confirmed periprosthetic infection by gram stain or culture (pain and functional disability are not required in the presence of confirmed periprosthetic infection);
2. Aseptic loosening of one or more prosthetic components confirmed by imaging;
3. Periprosthetic fracture of distal femur, proximal tibia, patella or any components of the prosthesis confirmed by imaging;
4. Worn bearing surface or plastic insert confirmed by imaging;
5. Progressive or substantial periprosthetic bone loss confirmed by imaging;
6. Malalignment or malposition of prosthesis confirmed by imaging;
7. Knee arthrofibrosis;
8. Instability or dislocation of one or more prosthetic components confirmed by imaging;
9. Documented persistent knee pain of unknown etiology with gait disturbance.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## Key Points:

Conservative Treatment

Before proceeding to total knee arthroplasty for an indication of osteoarthritis, a multifaceted regimen of nonoperative treatment should be attempted. Nonoperative treatments of knee OA are often useful for patients with Kellgren and Lawrence Grades (K-L scores) 1 to 3, which are "early" stages of OA. In this system, Grade 1 is characterized by doubtful joint space narrowing and possible osteophytic lipping; Grade 2, by definite osteophytes and possible joint space narrowing on anteroposterior weight-bearing radiograph; Grade 3, by multiple osteophytes, definite joint space narrowing, sclerosis, and possible bony deformity; and Grade 4, by large osteophytes, marked joint space narrowing, severe sclerosis, and definite bony deformity.

Guidelines from the American Academy of Orthopedic Surgeons (AAOS), the American College of Rheumatology, and the Osteoarthritis Research Society all suggest that patients be offered non-pharmacologic therapy including strengthening, stretching, and conditioning exercises; supervised physical therapy; weight reduction as appropriate; pharmacologic therapy, such as acetaminophen and nonsteroidal anti-inflammatory agents for patients who do not have contraindications; a trial of therapeutic injections; and use of wedge insoles or bracing.

Exercise and muscle strength building programs have been shown to be effective in alleviating some of the symptoms of knee OA including restoring range of motion, alleviating pain, and increasing ability to perform ADLs.

A recent randomized, assessor blinded, controlled trial (RCT) conducted by Skou and colleagues compared the outcomes of participants with moderate to severe knee OA who were assigned to either undergo total knee replacement (n=50) followed by 12 weeks of non-surgical treatment or 12 weeks of non-surgical treatment only (n=50). Non-surgical treatment consisted of exercise, education on the disease and self-help strategies, dietary counseling, use of insoles and pain medication. Participants were followed for 12 months. At 12 months, the difference in change of the mean score on four Knee Injury and Osteoarthritis Outcome Score (KOOS) subscales from baseline was calculated. In the intention-to-treat analysis, the surgically treated group reported a significantly greater improvement in KOOS score compared to the non-surgical group (32.5; 95% CI, 26.6 to 38.3 versus 16.0, 95% CI, 10.1 to 21.9) with an adjusted mean difference of 15.8 (95% CI, 10.0 to 21.5). Both groups did report clinically relevant improvements. The surgical group also reported significantly greater improvement in scores in secondary outcomes which assessed function, mobility and perceived quality of life. In the non-surgical group, 26% (13/50) had undergone a total knee replacement prior to the 12 month follow-up and 2% (1/50) of the surgical group had not undergone total knee replacement at 12 months. These individuals were included in the intention-to-treat analysis. Serious adverse events were significantly higher in the surgical group versus the non-surgical group (8 versus 1; p=0.05 in the treated knee and 24 versus 6, p=0.005 overall). Adverse events included deep venous thrombosis and stiffness requiring manipulation under anesthesia. While the surgical group did show a greater improvement in decreasing pain and improving function and quality of life, the risk of serious adverse events is also increased. The non-surgical group was also found to have substantial improvement in most outcomes. While the results of this study did support that total knee replacement does provide improved outcomes over non-surgical treatment in those with moderate to severe OA, the surgery is not without risks. Non-surgical treatment should be pursued prior to elective surgery in order to maximize any potential benefits while minimizing risks.

Obesity

An association between obesity (body mass index) and the prevalence and incidence of knee OA has been consistently demonstrated in several cross-sectional and longitudinal studies. Although excess weight increases joint loading, resulting in deleterious effects on weight-bearing joints, this is not the only factor involved in the relationship between OA and obesity. Obesity increases the risk of knee OA by multiple mechanisms: Increased joint loading; changes in body composition, with negative effects related to inflammation; and behavioral factors, such as diminished physical activity and subsequent loss of protective muscle strength. Weight loss not only reduces the risk of incident knee OA but, in established disease, also reduces symptoms, improves function, and may reduce disease progression. Furthermore, it is expected that the prevalence of obesity is unlikely to decline and will probably increase the incidence of knee OA and the demand for knee arthroplasty.

Obesity is an independent risk factor for multiple diseases including joint deterioration. Excessive body weight increases the major mechanical load on the knee and contributes to

changes in the composition, structure, and mechanical properties of articular cartilage. Zhou and colleagues evaluated the impact of BMI on the risk of knee OA in a meta-analysis of 12 studies. The authors discovered a significant non-linear dose-response association between BMI and the risk of OA. When compared with a baseline BMI of 22.5 kg/m2, at 25 kg/m2, the relative risk (RR) increase was 1.59 (95% confidence interval [CI], 1.34-1.81). A BMI of 30 kg/m2 increased RR by 3.55 (95% CI, 2.51-5.11), at a BMI of 35 kg/m2 the RR was 7.45 (95% CI, 4.19-13.13) (p=0.000).Within the overall population, the increase in the incidence of total joint arthroplasty parallels the rising rate of obesity. There is a general consensus that the risk of short term post-operative complications increases as weight increases, including wound infections, component malposition and in-hospital mortality. In a retrospective analysis, D'Apuzzo and colleagues suggested that obesity itself is not an independent risk factor for in-hospital complications and that the multiple comorbidities associated with obesity are significant confounders in many studies. In addition, there is conflicting evidence regarding whether obese individuals benefit from improved clinical outcomes in the long term. There does appear to be an increased revision rate for overweight or obese individuals five or more years following the initial surgery although this risk appears to be only moderately higher. Obese individuals have reported equivalent or superior clinical outcome satisfaction scores. There appears to be few options for those individuals with DJD who are overweight or obese. Smith noted that those individuals with OA are at a greater risk of gaining weight due to reduced activity. While the authors of many of the studies recognized the increased complexity related to performing TKAs on this population, the majority of studies recommended not withholding joint replacement surgery for overweight or obese individuals. The American Association of Hip and Knee Surgeons notes that TKA may be considered in obese individuals and states “expectations are for a steady, but slower improvement in the severe obese compared to non-obese patients post operatively”.

**Indications for Knee Arthroplasty**

Degenerative Joint Disease

Osteoarthritis (OA) of the knee is a progressive disease that ultimately damages the entire joint and is the leading indication for joint replacement surgery; 905,000 knee and hip replacements were performed in 2009 at a cost of 42.3 billion dollars. Knee OA should initially be treated conservatively, but surgery should be considered if symptoms persist. Surgical treatments for knee OA include arthroscopy, osteotomy, and knee arthroplasty; determining which of these procedures is most appropriate will depend on several factors, including the location and severity of OA damage, patient characteristics, and risk factors. Arthroscopic lavage and debridement do not alter disease progression, and should not be used as a routine treatment for the osteoarthritic knee. Bone marrow stimulation techniques such as microfracture are primarily used to treat focal chondral defects; the evidence for the use of these techniques for knee OA remains unclear. For patients with severe OA, total knee arthroplasty can be a safe and effective treatment.

In a 2011 study, Löfvendahl et al compared selected indication parameters for patients scheduled for hip and knee replacement at orthopaedic units in Sweden. The study time was from June 2006 to June 2008. The study subjects were patients undergoing hip or knee replacement for osteoarthritis (OA). For data collection, the study included a Swedish priority criteria tool based on a translation from a form used in Canada with minor changes. The reliability and validity of the Swedish tool were investigated, with good reproducibility. The questionnaires (one for the doctor and one for the patient) were completed during decision making for surgery. Eleven

hospitals enrolled in the study. In total, 2961 patients were included during the study period. Among these, 1662 were hip replacement patients and 1299 were knee replacement patients. The vast majority of patients undergoing hip or knee replacement had findings indicating severe OA, both clinically and radiologically according to the clinical priority tool. Statistically significant self-reported problems with pain at rest, walking and impaired activities of daily living were also observed. There were statistically significant differences in reported indications between the hospitals, both for hip OA patients and for knee OA patients. This study concluded that a clinical priority criteria tool is a useful means of following changes in indications for certain procedures. It could also contribute to explaining differences in case mix when evaluating clinical outcome and patient satisfaction.

Post-traumatic Arthritis

There is paucity in the literature regarding the effectiveness of total knee arthroplasty for the treatment of post-traumatic arthritis (PTA). PTA refers to structural damage following an injury to an articulating joint. It commonly affects younger, more active individuals as they are more likely to participate in such activities that may cause injury (i.e., sports, blunt trauma, motor vehicle accidents, etc.). It is estimated that 12% of all symptomatic osteoarthritis (OA) of the hip, knee, and ankle are due to PTA. With a varied prevalence of 21%-44% reported in the literature, PTA of the knee occurs following intra- or extra-articular fractures of the proximal tibia, patella, and distal femur. A combination of factors most likely contributes to the development of PTA following injury to the knee. First, mechanical imbalance may be due to ligamentous laxity, meniscal tears and malalignment. Second, the release of pro-inflammatory cytokines into local tissue leads to imperfect remodeling of the cartilage. Lastly, non-unions and malunions following fractures may lead to PTA. In regards to treatment of PTA, conservative management, including activity modification, anti-inflammatory medications, ambulatory assist devices, and physical therapy are exhausted before proceeding to surgical option. Surgical management ranges from arthroscopic debridement to arthrodesis. Total knee arthroplasty is an option for the treatment of end-stage PTA. Compared to TKA for patients with primary OA, TKA performed for PTA is often more technically challenging due to previous surgeries and scarring, uses more hospital resources, and incurs a higher cost. There are conflicting reports in the literature regarding the short and long term outcomes of these surgeries, as well as associated perioperative complications.

In a systematic review by Saleh et al in 2016, 16 studies (prospective and retrospective) examined patients who underwent TKA for PTA due to fractures of the proximal tibia, patella, and/or distal femur and assessed functional outcomes. The studies reported an improvement in functional and knee scores of patients following TKA with increased range of motion (ROM) and reduction of pain following surgery. The most commonly reported complications with TKA included infection, stiffness, wound complications, intraoperative rupture of tendons, and osteolysis/polyethylene wear. The overwhelming majority of these complications occurred within the first 2 years following surgery. Six studies examined the survivorship of TKA with subsequent revision for any reason as an endpoint. Compared to patients with osteoarthritis, patients with PTA required more revisions, the majority for polyethylene wear. Although associated with higher complication rates, TKA is an effective treatment for PTA, as it improves ROM, pain and functional outcomes.

Rheumatoid Arthritis

Total knee arthroplasty in patients with rheumatoid arthritis (RA) presents several unique challenges. Patients with RA often have additional medical, anesthetic, and global musculoskeletal problems that are not present in the patient with osteoarthritis. Regarding the knee, these patients usually have osteopenia and may present with an array of bone and soft tissue deformities, each of which can impact the initial success and long term durability of a total knee replacement. Despite these potential difficulties, the early and long term results of total knee arthroplasty in patients with rheumatoid arthritis have a reported success rate for in excess of 85% at 10 years. The relative benefits of TKA were described in a 2015 study, by Dusad and colleagues, that compared the impact of total knee revision in patients with RA and with OA who were participants in the National Data Bank for Rheumatic Diseases and underwent such surgery between 1999 and 2012. A smaller proportion of patients with RA than OA underwent TKA (5.3% of 15,818 versus 10.2% of 3079 patients). The patients with RA had less preoperative pain but more involvement of other joints, underwent TKA at a younger age, and showed less improvement in most pain- and health-related quality of life measures, although both of the latter groups exhibited benefit. Revision rates due to septic or aseptic loosening are low. Problems with the patellofemoral articulation, including patellar instability, loosening, fracture, and component failure, are a leading cause of the need for TKA reoperation. In a prospective study of all TKAs from the Norwegian arthroplasty register, a 1.6-fold higher risk of revision surgery due to infection was found in RA patients compared with OA patients. Removal and delayed replacement of the knee prosthesis may result in the best functional results.

Fractures and Malunion/Nonunion of Fractures

Bohm et al completed a review considering the surgical treatment of displaced fractures involving the knee in elderly, osteoporotic patients. The goals of treatment include pain control, early mobilization, avoidance of complications and minimizing the need for further surgery. Open reduction and internal fixation (ORIF) frequently results in loss of reduction, which can result in post-traumatic arthritis and the occasional conversion to total knee replacement. TKA after failed internal fixation is challenging, with modest functional outcomes and high complication rates. TKA undertaken as treatment of the initial fracture has better results to late TKA, but does not match the outcome of primary TKA without complications. Given the relatively infrequent need for late TKA following failed fixation, ORIF is the preferred management for most cases. Early TKA can be considered for those patients with pre-existing arthritis, bicondylar femoral fractures, those who would be unable to comply with weight-bearing restrictions, or where a single definitive procedure is required.

Primary cemented arthroplasty of the knee is a viable alternative to open reduction and internal fixation (ORIF) for treatment of osteoporotic fractures about the knee. This permits early return of knee function and weight bearing activity. Stemmed revision total knee arthroplasty implants and techniques are needed, which can be associated with complications of late loosening and periprosthetic fracture. However, for elderly sedentary patients who would not be expected to outlive the durability of the arthroplasty and with fracture patterns in which ORIF may be associated with poor outcomes, primary arthroplasty can be a favorable treatment option.

Limb Salvage for Malignancy

The use of knee arthroplasty to reconstruct a knee following the diagnosis of a primary or metastatic tumor has largely replaced amputation as the treatment of choice. In appropriate candidates, arthroplasty can allow the individual to retain a higher level of function. In a systematic review, Thambapillary and colleagues evaluated the longevity, complications and functional outcomes associated with proximal femoral arthroplasty to treat primary or metastatic tumors of the femur. The authors noted that in those with high-grade localized or metastatic disease, knee arthroplasty provided relief of pain and good functional capacity and tended to outlive the individual. In those with low-grade pathology, the limb salvage rate was reported at over 90% following curative resection margins surgery.

Frink et al evaluated implant survival, late complications prompting reoperation and functional outcome in long-term (greater than 5 years) survivors of bone neoplasms of the distal femur treated with osteoarticular resection and segmental rotating hinge total knee arthroplasty. Retrospectively reviewed were 83 patients who survived more than 5 years after the first procedure. Seventy-four of the 83 patients have retained a mobile knee joint. At a median follow-up of 146 months (range, 62-252 months), 22 patients required 26 additional procedures for a prosthesis-specific event (n = 24) or tumor recurrence (n = 2) after reaching 5-year follow-up. Aseptic loosening (n = 7) and component breakage (n = 2) occurred between 5 and 10 years. Polyethylene wear (n = 12) occurred only after 10 years. One late tumor recurrence at 62 months prompted amputation. All other patients retained a mobile knee joint. Functional outcome was excellent with a median Musculoskeletal Tumor Society score of 88% and a median Toronto Extremity Severity Scale score of 94%. Patients with bone neoplasms who survive more than 5 years after limb salvage with a segmental rotating hinge total knee arthroplasty can expect to retain a mobile knee joint and function consistently at a high level. The level of evidence for this study is as follows: Therapeutic study, Level III-2 (retrospective cohort study).

Avascular Necrosis (Osteonecrosis)

After the femoral head, the knee is the second most frequent location for secondary osteonecrosis (approximately 10% of the incidence of the hip). Osteonecrosis of the knee comprises two separate disorders, primary spontaneous osteonecrosis which is often a self-limiting condition and secondary osteonecrosis which is associated with risk factors and a poor prognosis.

Treatment recommendations often depend upon distinguishing between three pathologic disorders: secondary osteonecrosis, spontaneous osteonecrosis of the knee (SPONK), and post-arthroscopic osteonecrosis. The initial management of SPONK and post-arthroscopic osteonecrosis is to manage nonsurgically. By contrast, nonsurgical management is not recommended for secondary osteonecrosis, because approximately 80% of these patients will progress to needing a total knee arthroplasty within six years. Joint-preserving procedures include core decompression or percutaneous drilling and bone grafting of the lesion.

Despite early intervention with joint-preserving procedures, secondary osteonecrosis often proceeds to degeneration of the joint requiring arthroplasty. Both unicompartmental and total knee arthroplasties may be performed. In a study comparing total knee replacement before and after 1985, significant improvement in outcome results was noted for total knee replacement

after 1985 with 97% of patients having a good outcome as indicated by clinician-based assessments and by a 3% revision rate.

**Unicompartmental (Partial) Knee Replacements**

Kim et al investigated the long-term clinical results and survival rate of minimally invasive unicompartmental knee arthroplasty (UKA) by collecting cases that had been implanted more than 10 years ago. One hundred and twenty-eight patients (166 cases) who underwent Oxford phase 3 medial UKA using the minimally invasive surgery from January 2002 to December 2002 were selected. The mean age of the patients at the time of surgery was 61 years, and the duration of the follow-up was minimum 10 years. Clinical and radiographic assessments were performed using the Knee Society clinical rating system, and the survival analysis was done by the Kaplan-Meier method with 95% confidence interval (CI). The mean Knee Society knee and function scores improved significantly from 53.8 points (range, 25 to 70 points) and 56.1 points (range, 35 to 80 points) preoperatively to 85.4 points (range, 58 to 100 points) and 80.5 points (range, 50 to 100 points) at 10-year follow-up, respectively ($p < 0.001$). Failures following the UKA occurred in 16 cases (9.6%), and the mean time of the occurrence of the failure was 6.2 years after the surgery. The 10-year survival rate was 90.5% (95% CI, 85.9 to 95.0) when failure was defined as all the reoperations, whereas the 10-year survival rate was 93.4% (95% CI, 89.6 to 97.1) when the cases in which only revision total knee arthroplasty was defined as failure. The results of this study show outstanding functions of the knee joint and satisfactory 10-year survival rate after minimally invasive UKA. Therefore, minimally invasive UKA could be a useful method in the treatment of osteoarthritis in one compartment of knee joint.

Kristensen et al reported partial knee arthroplasty (PKA) has shown obvious advantages compared to total knee arthroplasty, but survival of PKA from different institutions and registries has differed. In a single institution, 695 consecutive Oxford medial PKAs were performed from 2002 to 2011 with mean follow-up of 4.6 years. The overall 10.7-year survival rate was 85.3% (95% CI: 78.7%-90.0%), and no difference in survival for gender and age younger or older than 60 years was found. One year after PKA, 94.3% were very satisfied or satisfied, as were 93.6% six years postoperatively. The revision rate was 7.3% (n=51), and the most common causes for revision were progression of osteoarthritis (n=16), aseptic loosening (n=11), and pain without loosening (n=10). Only 50% of patients revised for pain without loosening had a satisfactory outcome.

Smith et al reported isolated unicompartmental knee arthritis is less common laterally than medially. Lateral unicompartmental knee arthroplasty (UKA) constitutes only 1% of all knee arthroplasty performed. Use of medial UKA is supported by several published series showing good long-term survivorship and patient satisfaction, in large patient cohorts. Results of lateral UKA however have been mixed. The authors presented the short and mid-term survivorship and 5-year clinical outcome of 101 lateral UKAs using a single prosthesis. Over a 9 year period, 100 patients who satisfied inclusion criteria underwent a lateral fixed-bearing unicompartmental arthroplasty. American Knee Society (AKSS), Oxford Knee (OKS) and modified Western Ontario McMaster Universities Arthritis Index (WOMAC) scores were completed preoperatively and at 1, 2 and 5years postoperatively. Kaplan-Meier survival analysis was used to determine the 2-year and 5-year survivorship, using revision for any cause as end point. Survivorship was 98.7% and 95.5% at 2 and 5years respectively. 1 knee was revised for subsidence of the tibial

component and 1 knee for progression of medial compartment osteoarthritis. Of a possible 35 knees in situ at 5 year follow-up, 33 knees were fully scored. Median AKSS, OKS and modified WOMAC scores were 182, 41, and 16 respectively. The authors concluded the mid-term survivorship and outcome scores at 5-years suggest that lateral unicompartmental knee arthroplasty provides a valuable alternative to total joint replacement in selected patients with isolated lateral tibio-femoral arthritis at mid-term follow-up.

Bolognesi et al assessed trends in the use of unicompartmental and total knee arthroplasty, associated durations of hospital stay, and postoperative outcomes from a nationally representative 5% sample of Medicare beneficiaries who were sixty-five years of age or older and who had undergone either unilateral unicompartmental knee arthroplasty or unilateral total knee arthroplasty from 2000 to 2009. The outcome measures were the rates of implant revision or removal within five years and the rates of periprosthetic infection, thromboembolic events, myocardial infarction, and all-cause mortality within one year. We conducted Kaplan-Meier analyses to assess the cumulative incidence of unadjusted outcomes and used Cox proportional-hazards regression to understand the relative risks of the outcomes for each procedure. A total of 68,603 patients underwent unilateral total knee arthroplasty (n = 65,505) or unilateral unicompartmental knee arthroplasty (n = 3098) from 2000 to 2009. The mean age was seventy-five years; 34% of the patients were men, and 92% were white. The procedure rate was twenty-one times higher for total knee arthroplasty (597 per 100,000 person-years) than unicompartmental knee arthroplasty (twenty-nine per 100,000 person-years). The use of total knee arthroplasty increased 1.7-fold, and the use of unicompartmental knee arthroplasty increased 6.2-fold. The mean length of stay (and standard deviation [SD]) was 3.9 ± 2.1 days for total knee arthroplasty and 2.4 ± 1.7 days for unicompartmental knee arthroplasty. The five-year revision rate was 3.7% for total knee arthroplasty and 8.0% for unicompartmental knee arthroplasty. After multivariable adjustment, the risk of revision remained 2.4 times higher for unicompartmental knee arthroplasty than for total knee arthroplasty (95% confidence interval [CI] = 2.03 to 2.83). After multivariable adjustment, patients who underwent unicompartmental knee arthroplasty had no significant differential one-year risk of infection (adjusted hazard ratio [HR] = 0.74; 95% CI = 0.55 to 1.01), thromboembolic events (adjusted HR =0.86; 95% CI = 0.57 to 1.29), or mortality (adjusted HR = 0.75; 95% CI = 0.50 to 1.11). The authors concluded although unicompartmental knee arthroplasty accounted for only 4.5% of the unilateral knee replacements among Medicare beneficiaries, the use of this procedure has increased dramatically. Compared with those who had total knee arthroplasty, patients who underwent unicompartmental knee arthroplasty had higher revision rates but shorter durations of stay and tended to have lower rates of perioperative complications. The authors noted these findings need to be confirmed by studies that incorporate detailed clinical information.

**Revision of Knee Arthroplasty**

Per Hamiltion et al, the rate of TKA revisions has held steady at approximately 8-12%, the overall number of cases has risen as the number of initial surgeries has increased. Complications can occur at any time during the post-operative period. Early failure may be the result of infection while later failures are due to device failure. As the mean life expectancy increased, the number of individuals outliving their device has increased. Individuals undergoing TKA at age 47 are two times as likely to require revision as to die. In contrast, individuals greater than 77 years old at the time of TKA had a 90% chance of dying prior to requiring revision due to device

failure. The most common causes of revision surgery, after device failure, are aseptic loosening, and infections. Revision surgery varies in terms of the extent of revision needed. The procedure may involve a relatively minor secondary patellar resurfacing and exchange of the tibial insert, or may require implantation of constrained linked and mega prostheses.

Sharkey et al conducted a study to determine the frequency and cause of failure after total knee arthroplasty and compare the results with those reported by a similar investigation conducted 10years ago by the same group. In this review, a total of 781 revision TKAs performed at a single institution over the past 10 years were identified. The most common failure mechanisms were: loosening (39.9%), infection (27.4%), instability (7.5%), periprosthetic fracture (4.7%), and arthrofibrosis (4.5%). Infection was the most common failure mechanism for early revision (<2years from primary) and aseptic loosening was the most common reason for late revision. Polyethylene (PE) wear was no longer the major cause of failure. Compared to the previous report, the percentage of revisions performed for polyethylene wear, instability, arthrofibrosis, malalignment and extensor mechanism deficiency has decreased.

Pitta and colleagues sought to determine the mechanism of failure among primary total knee arthroplasties performed at a single high volume. From May 2007 to December 2012, 18,065 primary TKAs performed on 16,083 patients at a single institution were recorded in a prospective total joint arthroplasty registry with a minimum of 5-year follow-up. We retrospectively reviewed patient charts to determine a cause of failure for primary TKAs. The most common reasons for failure within 2 years after TKA were infection and stiffness. The multivariable regression identified the following preoperative risk factors for TKA failure: history of drug abuse (hazard ratio [HR] 4.68; P = 0.03), deformity/mechanical preoperative diagnosis (HR 3.52; P < .01), having a constrained condylar knee implant over posterior-stabilized implant (HR 1.99; P < .01), post-traumatic/trauma preoperative diagnosis

(HR 1.78; P = .03), and younger age (HR 0.61; P < .01). These findings add to the growing data that primary TKAs are no longer failing from polyethylene wear-related issues. This study identified preoperative risk factors for failure of primary TKAs, which may be useful information for developing strategies to improve outcomes following TKA.

Evidence of progressive and substantial bone loss alone is sufficient reason to consider revision in advance of catastrophic prosthesis failure. Fracture or dislocation of the patella, instability of the components or aseptic loosening, infection, and periprosthetic fractures are common reasons for total knee revision.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

## Key Words:

Total knee replacement, total knee arthroplasty, TKA, patella arthroplasty, degenerative joint disease, DJD, knee osteoarthritis, unicompartmental knee replacement, partial knee replacement, knee revision, avascular necrosis of knee, osteonecrosis of knee, post-traumatic arthritis

## Approved by Governing Bodies:

Knee replacement surgery is a procedure and therefore is not regulated by the FDA. However, devices and instruments used during the surgery require FDA approval. See the following website for additional information (product codes MBH, JWH, KRO): www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

## Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

## Current Coding:

CPT Codes:

| | |
|---|---|
| **27445** | Arthroplasty, knee, hinge prosthesis (e.g., Walldius type) |
| **27446** | Arthroplasty, knee, condyle and plateau; medial OR lateral compartment |
| **27447** | Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty) |
| **27486** | Revision of total knee arthroplasty, with or without allograft; 1 component |
| **27487** | Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component |

## References:


1. American Academy of Orthopaedic Surgeons (AAOS). OrthoInfo: Arthritis of the knee. June 2014. Available at: orthoinfo.aaos.org/topic.cfm?topic=A00212.
2. American Academy of Orthopaedic Surgeons. Treatment of osteoarthritis of the knee. 2013, 2nd edition. www.aaos.org/research/guidelines/GuidelineOAKnee.asp.
3. Beard D, Price A, Cook J, et al. Total or Partial Knee Arthroplasty Trial - TOPKAT: study protocol for a randomised controlled trial. Trials. 2013; 14:292.
4. Bohm ER, Tufescu TV, Marsh JP. The operative management of osteoporotic fractures of the knee: to fix or replace? Journal of Bone and Joint Surgery. British Volume 2012; 94(9):1160-1169
5. Bolognesi MP, Greiner MA, Attarian DE, et al. Unicompartmental knee arthroplasty and total knee arthroplasty among Medicare beneficiaries, 2000 to 2009. J Bone Joint Surg Am. 2013; 95(22):e174.
6. Carr AJ, Robertsson O, Graves S et al. Knee replacement. Lancet. 2012; 379(9823):1331-1340.

7. Chiang CC, Chen PQ, Shen MC, Tsai W. Total knee arthroplasty for severe haemophilic arthropathy: long-term experience in Taiwan. Haemophilia. 2008; 14:828-834.
8. Cross MB, Berger R. Feasibility and safety of performing outpatient unicompartmental knee arthroplasty. Int Orthop. 2014; 38(2):443-447.
9. D'Apuzzo MR, Novicoff WM, Browne JA. The John Insall Award: Morbid obesity independently impacts complications, mortality, and resource use after TKA. Clin Orthop Relat Res. 2015; 473(1):57-63.
10. Dusad A, Pedro S, Mikuls TR, Hartman CW, Garvin KL, O'Dell JR, Michaud K. Impact of total knee arthroplasty as assessed using patient-reported pain and health-related quality of life indices: Rheumatoid arthritis versus osteoarthritis. Arthritis Rheumatol. 2015; 67(9):2503.
11. Frink SJ, Rutledge J, Lewis VO et al. Favorable long-term results of prosthetic arthroplasty of the knee for distal femur neoplasms. Clinical Orthopaedics and Related Research. 2005; 438:65-70.
12. Golightly YM, Allen KD, Caine DJ. A comprehensive review of the effectiveness of different exercise programs for patients with osteoarthritis. Phys Sportsmed. 2012; 40(4):52-65.
13. Hamilton DF, Howie CR, Burnett R, et al. Dealing with the predicted increase in demand for revision total knee arthroplasty: challenges, risks and opportunities. Bone Joint J. 2015; 97-B(6):723-728.
14. Jorge RT, Souza MC, Chiari A, et al. Progressive resistance exercise in women with osteoarthritis of the knee: a randomized controlled trial. Clin Rehabil. 2015; 29(3):234-243.
15. Kerkhoffs GM, Servien E, Dunn W, et al. The influence of obesity on the complication rate and outcome of total knee arthroplasty: a meta-analysis and systematic literature review. J Bone Joint Surg Am. 2012; 94(20):1839-1844.
16. Kim KT, Lee S, Kim JH, et al. The Survivorship and Clinical Results of Minimally Invasive Unicompartmental Knee Arthroplasty at 10-Year Follow-up. Clin Orthop Surg. 2015; 7(2):199-206.
17. Kristensen PW, Holm HA, Varnum C. Up to 10-year follow-up of the Oxford medial partial knee arthroplasty--695 cases from a single institution. J Arthroplasty. 2013; 28(9 Suppl):195-198.
18. Kulkarni K, Karssiens T, Kumar V, Pandit H. Obesity and osteoarthritis. Maturitas. 2016 Jul;89: 22-28.
19. Kuwashima U, Okazaki K, Tashiro Y, et al. Correction of coronal alignment correlates with reconstruction of joint height in unicompartmental knee arthroplasty. Bone Joint Res. 2015; 4(8):128-133.
20. Latham N, Liu CJ. Strength training in older adults: the benefits for osteoarthritis. Clin Geriatr Med. 2010; 26(3):445-459.
21. Liddle AD, Judge A, Pandit H, Murray DW. Adverse outcomes after total and unicompartmental knee replacement in 101 330 matched patients: a study of data from the National Joint Registry for England and Wales. Lancet. 2014 Jul 7.
22. Lofvendahl S, Bizjajeva S, Ranstam J et al. Indications for hip and knee replacement in Sweden. J Eval Clin Pract. 2011; 17(2):251-260.
23. Lutzner J, Kasten P, Gunther KP et al. Surgical options for patients with osteoarthritis of the knee. Nat Rev Rheumatol. 2009; 5(6):309-316.

24. Manzotti A, Cerveri P, Pullen C, et al. A flat all-polyethylene tibial component in medial unicompartmental knee arthroplasty: a long-term study. Knee. 2014; 21 Suppl 1:S20-5.
25. Martin GM, Thornhill TS, Katz JN. Total knee arthroplasty. UpToDate. August 4, 2015.
26. Marulanda G, Seyler TM, Sheikh NH, Mont MA. Percutaneous drilling for the treatment of secondary osteonecrosis of the knee. J Bone Joint Surg Br. 2006; 88(6):740.
27. McElroy MJ, Pivec R, Issa K, et al. The effects of obesity and morbid obesity on outcomes in TKA. J Knee Surg. 2013; 26(2):83-88.
28. Miniaci A. UniCAP as an alternative for unicompartmental arthritis. Clinics in Sports Medicine. 33 (1) (pp 57-65), 2014.
29. Mont MA, Marker DR, Zywiel MG, Carrino JA. Osteonecrosis of the knee and related conditions. J Am Acad Orthop Surg. 2011 Aug; 19(8):482-494.
30. Mont MA, Tomek IM, Hungerford DS. Core decompression for avascular necrosis of the distal femur: long term followup. Clin Orthop Relat Res. Jan 1997.
31. Murphy, L., Helmick, CG. The impact of osteoarthritis in the United States: A population-health perspective. AM J Nurs. 2012; 112(3 Suppl 1):S13-19.
32. Murray DW, MacLennan GS, Breeman S, et al. A randomised controlled trial of the clinical effectiveness and cost-effectiveness of different knee prostheses: the Knee Arthroplasty Trial (KAT). Health Technol Assess. 2014; 18(19):1-235, vii-viii.
33. Myers TG, Cui Q, Kuskowski M, Mihalko WM, Saleh KJ. Outcomes of total and unicompartmental knee arthroplasty for secondary and spontaneous osteonecrosis of the knee. J Bone Joint Surg Am. 2006; 88 Suppl 3:76-82.
34. National Institutes of Health Consensus Panel. NIH Consensus Statement on total knee replacement December 8-10, 2003. J Bone Joint Surg Am. 2004; 86-(6):1328-1335.
35. Niinimäki T, Eskelinen A, Mäkelä K, et al. .Unicompartmental knee arthroplasty survivorship is lower than TKA survivorship: a 27-year Finnish registry study. Clin Orthop Relat Res. 2014; 472(5):1496-501.
36. Perry KI, MacDonald SJ. The obese patient: a problem of larger consequence. Bone Joint J. 2016; 98-B(1 Suppl A):3-5.
37. Pitta, Michael et al. Failure after modern total knee arthroplasty: A prospective study of 18,065 knees. J Arthroplasty. 2018; 33(2):407-414.
38. Punzi L, Galozzi P, Luisetto R, et al. Posttraumatic arthritis: overview on pathogenic mechanisms and role of inflammation. RMD Open 2016; 2:e000279.
39. Richmond JC. Surgery for osteoarthritis of the knee. Rheumatic Disease Clinics of North America. 2013; 39(1):203-211.
40. Ries MD. Primary arthroplasty for management of osteoporotic fractures about the knee. Current Osteoporosis Reports. 2012; 10(4):322-327.
41. Rijnen WH, Luttjeboer JS, Schreurs BW, Gardeniers JW. Bone impaction grafting for corticosteroid-associated osteonecrosis of the knee. J Bone Joint Surg Am. 2006; 88 Suppl 3:62-68.
42. Saleh H, Yu S, Vigdorchik J, Schwarzkopf R. Total knee arthroplasty for treatment of post-traumatic arthritis: Systematic review. World Journal of Orthopedics. 2016; 7(9):584-591.
43. Schrama JC, Espehaug B, Hallan G, Engesaeter LB, Furnes O, Havelin LI, Fevang BT. Risk of revision for infection in primary total hip and knee arthroplasty in patients with rheumatoid arthritis compared with osteoarthritis: A prospective, population-based study on 108,786 hip and knee joint arthroplasties from the Norwegian Arthroplasty Register. Arthritis Care Res (Hoboken). 2010 Apr; 62(4):473-479.

44. Sharkey, Peter F. et al. Why are total knee arthroplasties failing today: Has anything changed in 10 years? J Arthroplasty. 2014; 29(9): 1774–1778.
45. Si HB, Zeng Y, Shen B, et al. The influence of body mass index on the outcomes of primary total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2015; 23(6):1824-1832.
46. Skou ST, Roos EM, Laursen MB, et al. A randomized, controlled trial of total knee replacement. N Engl J Med. 2015; 373(17):1597-1606.
47. Smith JR, Robinson JR, Porteous AJ, et al. Fixed bearing lateral unicompartmental knee arthroplasty-Short to midterm survivorship and knee scores for 101 prostheses. Knee. 2014 Aug; 21(4):843-847.
48. Strauss AC, et al. Outcome after total knee arthroplasty in haemophilic patients with stiff knees. Haemophilia. 2015; 21:e300.
49. Suleiman LI, Ortega G, Ong'uti SK, et al. Does BMI affect perioperative complications following total knee and hip arthroplasty? J Surg Res. 2012; 174(1):7-11.
50. Tanaka R, Ozawa J, Kito N, Moriyama H. Efficacy of strengthening or aerobic exercise on pain relief in people with knee osteoarthritis: a systematic review and meta-analysis of randomized controlled trials. Clin Rehabil. 2013; 27912):1059-1071.
51. Thambapillary S, Dimitriou R, Makridis KG, et al. Implant longevity, complications and functional outcome following proximal femoral arthroplasty for musculoskeletal tumors: a systematic review. J Arthroplasty. 2013; 28(8):1381-1385.
52. Werner BC, Kurkis GM, Gwathmey FW, Browne JA. Bariatric surgery prior to total knee arthroplasty is associated with fewer postoperative complications. J Arthroplasty. 2015; 30(9 Suppl):81-85.
53. Wluka AE, Lombard CB, Cicuttini FM. Tackling obesity in knee osteoarthritis. Nat Rev Rheumatol. 2013 Apr; 9(4):225-235.
54. Workgroup of the American Association of Hip and Knee Surgeons Evidence Based Committee. Obesity and total joint arthroplasty: a literature based review. J Arthroplasty. 2013; 28(5):714-721.
55. Zhou ZY, Liu YK, Chen HL, et al. Body mass index and knee osteoarthritis risk: a dose-response meta-analysis. Obesity (Silver Spring). 2014; 22(10):2180-2185.

## Policy History:

Medical Policy Group, February 2018 **(7)**: New policy addressing knee arthroplasty.
Medical Policy Administration Committee, March 2018
Available for comment March 2 through ~~April 15, 2018~~ (extended to) April 30, 2018