BSC7.10	Knee Arthroplasty for Adults		
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Section:	7.0 Surgery	**Page:**	Page 1 of 24

Policy Statement

I. Knee arthroplasty may be considered **medically necessary** when **all** of the following criteria have been met:
   A. The reason for the arthroplasty is osteoarthritis (OA), rheumatoid arthritis, osteonecrosis, or post-traumatic arthritis of the knee joint
   B. It is NOT for bicompartmental knee replacement, including bi-unicompartmental (two individual compartments in the same knee)
   C. It is NOT for a customized knee replacement, including **all** of the following:
      1. It does NOT use customized knee implant
      2. It does NOT use a "Gender specific" implant
   D. It does NOT use focal resurfacing of a single knee joint defect (e.g., HemiCAP™, UniCAP™)
   E. It does NOT use minimally invasive approaches to knee arthroplasty
   F. The individual has **one or more** of the following conditions:
      1. Degenerative joint disease when **all** of the following conditions exist:
         a. Documentation of unsuccessful conservative therapy (non-surgical medical management), or documentation of rationale if conservative therapy is considered inappropriate
         b. Documentation of limited range of motion, antalgic gait, and pain in knee joint with passive range of motion on physical examination
         c. Radiographic evidence of severe osteoarthritis as evidenced by **either** of the following:
            i. The presence of definite joint space narrowing with sclerosis and possible deformity of bone ends
            ii. The presence of large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of the proximal tibia or distal femur
      2. Distal femur fracture repair in a individual with osteoporosis
      3. Failure of a previous proximal tibial or distal femoral osteotomy
      4. Hemophilic arthroplasty
      5. Limb salvage for malignancy
      6. Posttraumatic knee joint destruction
      7. Replacement or revision of previous arthroplasty as indicated by **one or more** of the following conditions:
         a. Disabling pain
         b. Functional disability
         c. Progressive and substantial bone loss
         d. Fracture of patella
         e. Dislocation of patella
         f. Aseptic component instability
         g. Infection
         h. Periprosthetic fracture

II. Knee arthroplasty is considered **investigational** if the individual's situation does not meet the criteria above.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Conservative Treatment
As medically indicated, members with osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis should have non-surgical treatment documented in the medical record, including **all** of the following, unless contraindicated:

- Anti-inflammatory medications or analgesics
- Activity modification
- Supervised physical therapy which could include an instructed home exercise program, including flexibility and muscle-strengthening exercises. Post-op physical therapy visits will be allowed in addition to the pre-op physical therapy visits.
- Weight reduction counseling as appropriate
- Assistive device use (required for persons with certain relative contraindications to joint replacement, optional for others)
- Therapeutic injections into the knee as appropriate

Relative contraindications to joint replacement include the following: morbid obesity (BMI greater than 40), or age less than 50 years unless there are no other treatment options for the individual. Individuals with relative contraindications should exhaust all appropriate nonsurgical treatment options prior to surgical consideration.

Customized refers to something that is made specifically for that individual and could not be used for anyone else.

Description

Total Knee Arthroplasty (TKA), also known as Total Knee Replacement (TKR), is a surgical procedure to replace the weight-bearing surfaces of the knee joint to relieve pain and functional disability. The knee joint acts as a multiform hinge system to allow flexion, extension, rotation, and gliding movement. The lateral, medial, and patellofemoral compartments make up the knee joint. TKA is one of the most common orthopedic procedures performed, especially for osteoarthritis (OA), and also for other knee diseases such as rheumatoid arthritis, osteonecrosis, or post-traumatic arthritis of the knee joint that cannot be resolved by conservative therapy.

Related Policies

- Hip Arthroplasty for Adults

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Knee replacement surgery is a procedure and therefore is not regulated by the U.S. Food and Drug Administration (FDA). However, devices and instruments used during the surgery require FDA approval and are regulated by the FDA through the 510(k) marketing process. Knee joint prostheses are regulated by the FDA as Class II devices.

Rationale

Background
Total knee arthroplasty (TKA) is commonly performed for the relief of arthritis associated knee pain in patients who have failed conservative therapy. TKA is indicated when 2 or 3 compartments are affected. The lifespan of the prosthetic joint is limited and based on variables including patient age, comorbidities, obesity, as well as prosthetic and surgical factors. Although a TKA can provide potential benefits and successful outcomes, it is an elective procedure and should only be considered after extensive discussion of the risks, benefits, and alternatives. The use of shared decision making aides and functional outcome measures have shown to improve a patient's knowledge of the options available, and allows a patient to have a more accurate expectation of possible benefits and harm of their options.

In certain circumstances, a trial of conservative treatment is warranted prior to TKA. Conservative therapy (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 is considered an appropriate option.

According to the American Academy of Orthopaedic Surgeons (AAOS), the following defines TKA and provides the TKA process:

A knee replacement (also called knee arthroplasty) might be more accurately termed a knee "resurfacing" because only the surface of the bones are actually replaced.
There are four basic steps to a knee replacement procedure.

- **Prepare the bone:** The damaged cartilage surfaces at the ends of the femur and tibia are removed along with a small amount of underlying bone.
- **Position the metal implants:** The removed cartilage and bone is replaced with metal components that recreate the surface of the joint. These metal parts may be cemented or "press-fit" into the bone.
- **Resurface the patella:** The undersurface of the patella (kneecap) is cut and resurfaced with a plastic button. Some surgeons do not resurface the patella, depending upon the case.
- **Insert a spacer:** A medical-grade plastic spacer is inserted between the metal components to create a smooth gliding surface.

The operation usually involves postoperative pain, and includes intense physical rehabilitation. The recovery period may be 6 weeks or longer and may require assistive device use (e.g., canes, crutches, walkers) to enable the patient to return to their preoperative, functional level.

The surgery may be more complicated and be at a higher risk for postop complications in patients with severe deformity from advanced rheumatoid arthritis, trauma, or long-standing osteoarthritis. It is not common for osteoporosis to cause knee pain, deformity, or inflammation and is not a reason to perform knee replacement, unless a patient with osteoporosis requires a distal femur fracture repair.

TKA is a safe and cost-effective treatment for mitigating pain and restoring physical mobility in patients who do not respond to conservative therapy (non-surgical medical management). TKA has

been shown to be a very successful, somewhat low-risk therapy despite variations in patient health status and characteristics, type of prosthesis implanted, orthopaedic surgeons, and surgical facilities. There are few contraindications to this surgery as it is currently used, therefore improvements can be made in the overall success of TKA by addressing each of these areas of variation through further research:

- Approximately 300,000 TKA surgeries are performed each year in the United States for end-stage arthritis of the knee joint. As this number rises and the indications for TKA extend to younger as well as older patients, a review of available scientific information is necessary to amplify clinical decision-making and promote further research.
- First used in the late 1950s, early TKA implants poorly mimicked the natural motion of the knee and resulted in high failure and complication rates. Advances in TKA technology in the past 10 years have enhanced the design and fit of knee implants, resulting in improved short- and long-term outcomes. Although there is an increased success of TKA, questions remain concerning which materials and implant designs are the most adequate for specific patient populations and which surgical approach is ideal for a successful outcome.

Physical, social, and psychological issues may influence the success of TKA, and understanding patient differences could advance the decision making process before, during, and after surgery, thereby achieving the greatest benefit from TKA. Special attention must also be given to the treatment and timing options related to the revision of failed TKA surgery. Total knee arthroplasty improvements in surgical materials and techniques have greatly increased its performance. Total knee replacements are one of the most successful procedures in all of medicine and according to the Agency for Healthcare Research and Quality, more than 600,000 knee replacements are performed each year in the United States not only for OA, but also for other knee diseases such as rheumatoid arthritis, avascular necrosis, or post-traumatic arthritis of the knee joint.

Literature Review

Degenerative Joint Disease

Osteoarthritis (OA) of the knee is a progressive disease that ultimately damages the entire joint. 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, rewarding, and cost-effective treatment.

Swedish orthopaedic clinics performing joint replacement were invited to enroll in a study. The study time was set to 2 years (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.

According to Carr et al (2012), knee-replacement surgery is frequently done and highly successful. It relieves pain and improves knee function in people with advanced arthritis of the joint. The most common indication for the procedure is osteoarthritis. Epidemiology of and risk factors for knee replacement are reviewed. Because replacement is increasingly considered for patients younger than 55 years, improved decision making about whether a patient should undergo the procedure is needed. Assessment of surgery outcomes based on data for revision surgery from national joint-replacement registries and on patient-reported outcome measures are discussed. Widespread surveillance of existing implants is urgently needed alongside the carefully monitored introduction of new implant designs. Developments for the future are improved delivery of care and training for surgeons and clinical teams. In an increasingly ageing society, the demand for knee-replacement surgery will probably rise further, and we predict future trends. The need for new strategies to treat early-stage osteoarthritis, which will ultimately reduce the demand for joint-replacement surgery is emphasized. Current total knee arthroplasty designs can be expected to survive 20 years or more in the older, less active population. New materials may extend that survivorship.

Conservative Treatment

Before proceeding to total knee arthroplasty for an indication of osteoarthritis, a multifaceted regimen of nonoperative treatment should be attempted. Guidelines from the American Academy of Orthopedic Surgeons, 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; weight loss for those who are overweight; pharmacologic therapy, such as acetaminophen and nonsteroidal anti-inflammatory agents for patients who do not have contraindications; a trial of glucocorticoid injections; and use of wedge insoles or bracing.

According to the American Academy of Orthopaedic Surgeons (AAOS), nonsurgical medical management is usually but not always implemented prior to scheduling total knee arthroplasty surgery. Nonsurgical treatment as clinically appropriate for the patient's current episode of care typically includes one or more of the following:

- Anti-inflammatory medications or analgesics
- Flexibility and muscle strengthening exercises
- Supervised physical therapy [Activities of daily living (ADLs) diminished despite completing a plan of care]
- Assistive device use
- Weight reduction as appropriate
- Therapeutic injections into the knee as appropriate

Shared Decision Making (SDM)

Shared decision making (SDM) is promoted as an ideal model to incorporate in the treatment plan between patient and physician. This is based on the premise that the best medical decision for an individual patient incorporates the patient's preferences and values through the process of information sharing and planning. This idea involves at least two participants-the clinician and the patient. It represents the optimal physician-patient communication. Patients most likely to perceive their physicians as providing excellent care are those experiencing their preferred decision-making style with their primary physicians. Studies show that patient satisfaction, medication compliance, and health outcomes are improved by shared decision making.

On July 19, 2015, the first joint International Shared Decision-Making/International Society for Evidence-Based Health Care (ISDM/ISEHC) Conference met in Sydney, Australia with over 300 people from around the globe to share knowledge and inspire action to improve the entire health care experience. Highlights of this meeting included:

- Informed consents are gaining importance connected with the use of the SDM, which includes a collaborative conversation around the patient's informed preferences and the best available scientific evidence.
- Aligned incentives are necessary to maximize SDM, but not necessarily monetary.
- Increasing in interest and gaining support is the inclusion of family engagement in the decision-making process with the patient/family/care team (called a triad) rather than the patient/care team (called a dyad). The discussion was how to make this a reality, as it has long been felt the family needed to be part of the SDM, but not easily implemented.
- Development of learning programs/greater communication skills for medical students was repeatedly discussed, looking for ways to include training for these as learned skills to build conversations around patient preferences and evidence-based scientific medicine/practice.

Fracture

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.

Bohm et al (2012) 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 result in loss of reduction, which can result in post-traumatic arthritis and the occasional conversion to total knee replacement (TKR). TKR after failed internal fixation is challenging, with modest functional outcomes and high complication rates. TKR undertaken as treatment of the initial fracture has better results to late TKR, but does not match the outcome of primary TKR without complications. Given the relatively infrequent need for late TKR following failed fixation, ORIF is the preferred management for most cases. Early TKR 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.

Total Knee Replacement Revision

Rates of prosthesis failure requiring revision increase with duration of follow-up after surgery from about 10 percent at 10 years to about 20 percent at 20 years (~1 percent per year). Prosthesis failure rates vary substantially across studies; factors associated with shortened time to prosthesis failure include age younger than 55 years, male gender, diagnosis of OA, obesity, and presence of comorbid conditions. It is hypothesized that the higher rate of prosthesis failure observed in young obese men with OA is related to higher levels of physical activity after TKR in this population. In general, prostheses are durable, but failure does occur. Because the most common treatment for prosthesis failure is revision of the TKR, the incidence of revision is commonly used as a measure of prosthesis failure. The role of gender on failure rate is variable depending on the study. Data based on two large studies (Sweden and Canada) demonstrate that gender has no influence on revision rates among patients with OA. However, an American study demonstrated that men had an overall greater risk of failure than women. Among patients with RA, the risk of failure was greater in men than in women. In addition, younger men who are obese appear to be at substantially higher risk of revision than other patients, especially compared with older, nonobese women. As the cumulative incidence of primary

TKR increases, as indications extend to older and younger individuals, and as the population ages, the absolute number of revision knee replacements will increase even if the rate of failures in primary procedures continues to decrease. Revision surgery is complex and costly, requires technical expertise, and should be performed in high-quality hospitals by skilled health care teams. Consequently, the surgeon's experience, hospital characteristics, and related health care costs with revision should be examined carefully. As with primary TKR, revisions for failed TKR are done to alleviate pain and improve function. The goals of TKR revision are restoration of mechanical and rotational alignment, restoration of joint line and space, and achievement of stable implant fixation. It remains very important to refine the indications for revision and to do so on the basis of the best available outcome data. The decision to revise, as is true of decisions regarding primary procedures, must consider circumstances such as the presence of disabling pain, stiffness, and functional limitation unrelieved by appropriate nonsurgical management and lifestyle changes. The results of TKR revision are not as good as those of primary TKR, the former being approximately 70 percent in the good-to-excellent range whereas the latter is approximately 90 percent. Outcomes are better for patients who undergo revision for aseptic loosening as opposed to infection. The proportion of patients with good-to-excellent outcomes declines with each successive revision. It is critical to identify the cause of the original prosthesis failure to improve the outcome following revision surgery. Early loosening may result from poor surgical technique of the original TKR, infection, mechanical overload, or osteolysis. Osteolysis appears to result from an inflammatory reaction to particulate debris generated from the prosthesis. Efforts to minimize osteolysis include a search for more durable and wear-resistant materials. Research in management of osteolysis includes nonsurgical treatment, such as use of bisphosphonates and cytokine inhibitors. Periodic radiographic monitoring, as part of standard, long-term orthopaedic follow-up care, may allow appropriate management before prosthesis failure. A number of options must be considered in planning a revision operation. Current revision implants have been available only for the past decade and appear to improve results, although more long-term data are needed. Although the literature on revision TKR is limited, outcomes of revision for failed primary TKR show good results at 5 years, but long-term results are less certain. Revision for infection is a challenging problem, with the most successful functional results being obtained in a two-stage revision. Salvage procedures for failed revision TKR include the following:

- Resection arthroplasty (usually reserved for nonambulatory patients with persistent infections)
- Arthrodesis
- Above-the-knee amputation

A salvage procedure is eventually required in less than 10 percent of revised TKRs. The primary indication for a salvage procedure is an infected revised TKR. The limited data available indicate that pain relief and improved function following any of these salvage procedures are limited and far inferior to revision TKR. Age younger than 55 at the time of TKR, male gender, diagnosis of OA, obesity, and presence of comorbid conditions are risk factors for revision.

Other

Hemophilic Arthroplasty

Hemophilia is caused by a deficiency of clotting factor VIII or IX and is inherited by a sex-linked recessive pattern. von Willebrand disease, a common, moderate bleeding disorder, is caused by a quantitative or qualitative protein deficiency of von Willebrand factor and is inherited in an autosomal dominant or recessive manner. The most important clinical strategy for the management of patients with hemophilia is the avoidance of recurrent hemarthrosis by continuous, intravenous hematologic prophylaxis. Early hemarthrosis should be aggressively managed with aspiration and clotting factor concentrate until the joint examination is normal. Starting prophylactic factor replacement in infancy may prevent chronic synovitis and arthropathy. The natural history of poorly controlled disease is polyarticular hemophilic arthropathy; functional prognosis is poor. Patients with chronic synovitis may be treated effectively with radiosynovectomy; those who develop joint surface erosions may require realignment osteotomies, joint arthroplasty, and treatment of pseudotumors.

Reconstructive surgery for hemophilic arthropathy, especially in patients with factor inhibitor, requires careful hematologic management by an experienced, multidisciplinary team.

Limb Salvage for Malignancy

Frink et al (2005) 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).

Bicompartmental Knee Replacement

Bicompartmental knee arthroplasty features bone and ligament sparing as unicompartmental knee arthroplasty and is presumably better in the recovery of muscle strength and function compared to total knee arthroplasty (TKA) though not previously reported in the literature. The aim of the following study done by Chung et al (2013) was to compare isokinetic knee muscle strength and physical performance in patients who underwent either bicompartmental knee arthroplasty or TKA. Each of 24 patients (31 knees) was prospectively examined preoperatively, at 6 and 12 months after each surgery. Isokinetic knee extensor and flexor strength as well as position sense were measured using the Biodex system. Timed up and go test, stair climbing test, and the 6-min walk test were used to assess physical performance. The results of each group were also compared with those from the corresponding healthy control, respectively. Demography showed significant difference in the mean age between bicompartment (54.8 ± 5.6 years) and TKA groups (65.7 ± 6.7 years). Comparing between the two groups, knee extensor and flexor torque, hamstring/Quadriceps ratio, position sense, and physical performance were not significantly different preoperatively, at 6 and 12 months after surgery. In intra-group analysis, muscle strength and position sense at each time point were not different in both groups. In physical performance, both groups resulted in improvement in the 6-min walk test, and only TKA group showed enhancement in stair climbing test. Although theoretically plausible, bicompartmental knee arthroplasty was not superior in knee muscle strength and physical performance at 1 year compared with total knee arthroplasty.

Callahan et al (1995) completed a study to summarize the literature describing patient outcomes following unicompartmental and bicompartmental knee arthroplasty. Original studies were included in this meta-analysis if they enrolled 10 or more patients at the time of an initial knee arthroplasty and measured patient outcomes using a global knee rating scale. Forty-six studies on unicompartmental prostheses and 18 studies on bicompartmental prostheses met these criteria. For unicompartmental studies, the total number of enrolled patients was 2,391, with a mean enrollment of 47 patients and a mean follow-up period of 4.6 years. The mean patient age was 66 years; 67% were women, 75% had osteoarthritis, and 16% underwent bilateral knee arthroplasty. The mean postoperative global rating scale score was 80.9. The overall complication rate was 18.5% and the revision rate was 9.2%. Studies published after 1987 reported better outcomes, but also tended to enroll older patients and patients with osteoarthritis and higher preoperative knee rating scores. For bicompartmental studies, the total number of enrolled patients was 884, with a mean enrollment of 44 patients and a mean follow-up period of 3.6 years. The mean patient age was 61 years; 79% were women, 31% had osteoarthritis, and 29% underwent a bilateral arthroplasty. The mean postoperative

global rating scale score was 78.3. The overall complication rate was 30% and the revision rate was 7.2%. Although bicompartmental studies reported lower mean postoperative global rating scale scores, these studies tended to enroll patients with worse preoperative knee rating scores. Recent improvements in patient outcomes following unicompartmental knee arthroplasty appear to be due, at least partially, to changes in patient selection criteria. Patient outcomes appear to be worse for bicompartmental arthroplasties than for other prosthetic designs; however, patients enrolled in these studies had more poorly functioning knees before surgery and actually had greater absolute improvements in global knee rating scores.

Replacement of the patellofemoral and medial tibiofemoral joints has been performed since the 1980s. Bicompartmental replacement was modified. Two different designs were developed: one custom implant and one with multiple predetermined sizes. The surgical technique and instruments are unique, and training is helpful. There are no clinical reports for the custom design as of yet. The standard implant has several reports in the literature with only fair to good results and has subsequently been withdrawn from the market. Bicompartmental arthroplasty remains a questionable area of knee surgery. At present, the two separate implant technique is the best choice.

Customized Knee Replacement

Customized refers to something that is made specifically for that patient and could not be used for anyone else.

Customized knee replacement, according to ECRI Institute's Emerging Technology Evidence Report for "Total Knee Replacement Using Patient-Specific Templates" is as follows:

> Total knee replacement using commercially available patient-specific templates takes images from preoperative computed tomography (CT) or magnetic resonance imaging (MRI) scans to create single-use patient-specific templates intended to align knee implants.
>
> Surgeons use one of two methods to align knee implants. Using the more widely accepted method, the surgeon aims to resect the bones in the proper orientation in all planes so that the implant aligns to the mechanical axis of the leg. Generally, up to a 3° deviation from the mechanical axis is accepted to minimize the risk of implant collapse, wear, loosening, instability, and postoperative pain. An alternative alignment method uses three kinematic axes to align the knee implants. This kinematic-based alignment method considers the relative relationships of the femur, patella, and tibia through all flexion angles without applied force. Regardless of method, suboptimal alignment has been associated with shortened implant longevity and poor patient outcomes.
>
> Conventional instrumentation used during total knee replacement includes intramedullary and extramedullary guides to assist with proper orientation of femoral and tibial components. The use of conventional instrumentation has been reported to result in misalignment in approximately 28 percent of total knee replacements. Intraoperative computer-assisted navigation was developed to address alignment errors with conventional instrumentation. The use of intraoperative computer-assisted navigation has been reported to decrease the incidence of misalignment approximately threefold compared to conventional instrumentation.
>
> Total knee replacement using patient-specific templates is an alternative to conventional and intraoperative computer-assisted approaches for patients who are able to undergo MRI or CT and wait several weeks for processing and creation of the templates. During the surgery, the surgeon places the patient-specific templates on the ends of the patient's distal femur and proximal tibia and adjusts the position of the customized contact faces of each template until locating the exact fit to the bone. In some models, cutting guides within the templates specify where the surgeon should cut the bones, while other template models guide the insertion of pins, which then are used to place standard cutting guides. The surgeon creates the bone cuts, places the component replacement pieces, and uses cement to hold the pieces in place.

Purported benefits of using patient-specific templates during total knee replacement include the following:

- Improved alignment
- Decreased operative time
- Increased patient throughput
- Decreased instrumentation
- Reduced risk of fat embolism and intraoperative bleeding due to minimal bone removal (i.e., no intramedullary canal reaming)
- Decreased tissue loss
- Shorter recovery
- Reduced postoperative pain
- Decreased incidence of infection
- Lowered costs

State of Evidence Base for Customized Knee Replacement

Quantity of evidence: Low

The evidence base consists of two studies that met our inclusion criteria: one same-surgeon historical control study that assessed 51 patients and 1 prospective case series that assessed 48 patients.

Quality of evidence: Low

Limitations of the evidence base include lack of randomized controlled trials on patient-specific templates compared to conventional instrumentation; lack of data that compare patient-specific templates with intraoperative computer-assisted navigation; few outcomes reported; short follow-up; potential conflicts of interest in published studies; small study size; and data available on only one patient-specific templating system, OtisKnee. The included studies may also be underpowered to detect statistically and clinically significant differences in outcomes, and their small size prevents calculation of adverse event rates, especially uncommon and rare events, and generalizability of results.

Consistency of evidence: Low

Assessment of outcome consistency for range of motion, intraoperative blood loss, and operative time was not possible because only one study reported on these outcomes. No studies reported on alignment, stability, function, pain relief, quality of life, activities of daily living, durability, revision rate, conversion to conventional total knee replacement, and postoperative pain. The two studies composing the evidence base reported that no adverse events occurred during total knee replacement using patient-specific templates.

Minimally Invasive Approaches to Knee Arthroplasty

Although the primary goal of total knee arthroplasty is to relieve pain, the attainment of high flexion has emerged as an important secondary goal. Clinical pathways are evolving and focus on rapid recovery. The entire perioperative process for the patient and family, including office and hospital procedures, has been streamlined and patients are advised from the initial evaluation they will be able to quickly return to activities of daily living. Currently, patients are out of bed within hours of surgery, engaging in activities that require a substantial range of motion in the treated knee. They are frequently discharged directly to home within 24 to 48 hours. Lombardi et al (2006) retrospectively reviewed two groups of patients undergoing primary total knee arthroplasty whose perioperative management differed only by surgical approach, namely, standard versus less invasive. Refined perioperative protocols in combination with a less invasive, mini-arthrotomy approach using special instrumentation resulted in earlier discharge to home, higher range of motion and improved clinical and pain scores.

In minimally invasive knee replacement, the surgical procedure is similar, but there is less cutting of the tissue surrounding the knee. The artificial implants used are the same as those used for traditional knee replacement. However, specially designed surgical instruments are used to prepare the femur and tibia and to place the implants properly. Minimally invasive knee replacement is performed through a shorter incision-4 to 6 inches versus 8 to 10 inches for traditional knee replacement. A smaller incision allows for less tissue disturbance. In addition to a shorter incision, the technique used to open the knee is less invasive. In general, techniques used in minimally invasive knee replacement are "quadriceps sparing," meaning they avoid trauma to the quadriceps tendon and muscles in the front of the thigh. Other minimally invasive techniques called "midvastus" and "subvastus" make small incisions in the muscle but are also less invasive than traditional knee replacement. Because the techniques used to expose the joint involve less disruption to the muscle, it may lead to less postoperative pain and reduced recovery time. The hospital stay after minimally invasive surgery is similar in length to the stay after traditional knee replacement surgery--ranging from 1 to 4 days. Physical rehabilitation is a critical component of recovery. The surgeon or a physical therapist provides with specific exercises to help increase range of motion and restore your strength. Minimally invasive total knee replacement is not suitable for all patients. In general, candidates for minimal incision procedures are thinner, younger, healthier and more motivated to participate in the rehabilitation process, compared with patients who undergo the traditional surgery. Minimally invasive surgeries may be less suitable for patients who are overweight or who have already undergone other knee surgeries. In addition, patients who have a significant deformity of the knee, those who are very muscular, and those with health problems that may slow wound healing may be at a higher risk for problems from minimally invasive total knee replacement. Minimally invasive knee replacement is an evolving area and more research is needed on the long-term function and durability of the implants. The benefits of minimally invasive knee replacement have been reported to include less damage to soft tissues, leading to a quicker, less painful recovery and more rapid return to normal activities. Current evidence suggests that the long-term benefits of minimally invasive surgery do not differ from those of knee replacement performed with the traditional approach. Like all surgery, minimally invasive surgery has a risk of complications. These complications include nerve and artery injuries, wound healing problems, infection, and errors in positioning the prosthetic knee implants. Like traditional knee replacement surgery, minimally invasive surgery should be performed by a well-trained, highly experienced orthopaedic surgeon.

ECRI (2011) completed an evidence technology report concluding that Minimally Invasive Surgery (MIS) TKR resulted in a significantly greater improvement of KSS total scores at six month follow-up compared to conventional TKR and there were no differences in complication rates. Evidence reports that the data was insufficient to support conclusions for outcomes including but not limited to pain, function, activities of daily living, Oxford knee score, ability to walk independently, patient satisfaction and knee strength. ECRI documented that additional studies are needed to support long term outcomes and that MIS TKR outcomes are at least as good as those obtained with conventional TKR.

Fisher et al (2003) completed a retrospective radiographic analysis of implant position in minimally invasive unicompartmental knee arthroplasty (UKA), open UKA, and total knee arthroplasty (TKA). Implant position and limb alignment were recorded in the AP and lateral planes. Of the 3 groups evaluated, the total knee group had the least variation and greatest accuracy of implant placement and limb alignment. UKA groups had small but significant differences in postoperative alignment and AP tibial position. Using contemporary instrumentation, UKA is less accurate than TKA in implant placement and limb alignment. Minimally invasive UKA was not as accurate as open UKA in AP tibial placement or postoperative limb alignment.

Overutilization

Total knee arthroplasty (TKA) is one of the most common and costly surgical procedures performed in the United States. Cram et al (2012) completed a study to examine longitudinal trends in volume, utilization, and outcomes for primary and revision TKA between 1991 and 2010 in the US Medicare population. Observational cohort of 3,271,851 patients (aged =65 years) who underwent primary TKA

and 318,563 who underwent revision TKA identified in Medicare Part A data files. The study examined changes in primary and revision TKA volume, per capita utilization, hospital length of stay (LOS), readmission rates, and adverse outcomes. Between 1991 and 2010 annual primary TKA volume increased 161.5% from 93,230 to 243,802 while per capita utilization increased 99.2% (from 31.2 procedures per 10,000 Medicare enrollees in 1991 to 62.1 procedures per 10,000 in 2010). Revision TKA volume increased 105.9% from 9650 to 19,871 while per capita utilization increased 59.4% (from 3.2 procedures per 10,000 Medicare enrollees in 1991 to 5.1 procedures per 10,000 in 2010). For primary TKA, LOS decreased from 7.9 days (95% CI: 7.8-7.9) in 1991-1994 to 3.5 days (95% CI: 3.5-3.5) in 2007-2010 (P < .001). For primary TKA, rates of adverse outcomes resulting in readmission remained stable between 1991-2010, but rates of all-cause 30-day readmission increased from 4.2% (95% CI: 4.1%-4.2%) to 5.0% (95% CI: 4.9%-5.0%) (P < .001). For revision TKA, the decrease in hospital LOS was accompanied by an increase in all-cause 30-day readmission from 6.1% (95% CI: 5.9%-6.4%) to 8.9% (95% CI: 8.7%-9.2%) (P < .001) and an increase in readmission for wound infection from 1.4% (95% CI: 1.3%-1.5%) to 3.0% (95% CI: 2.9%-3.1%) (P < .001). Increases in TKA volume have been driven by both increases in the number of Medicare enrollees and in per capita utilization. Decreases in hospital LOS were accompanied by increases in hospital readmission rates.

The relationship between surgeon and hospital procedure volumes and clinical outcomes in total joint arthroplasty has long fueled a debate over regionalization of care. At the same time, numerous policy initiatives are focusing on improving quality by incentivizing surgeons to adhere to evidence-based processes of care. Bozic et al (2010) performed a study to evaluate the independent contributions of surgeon procedure volume, hospital procedure volume, and standardization of care on short-term postoperative outcomes and resource utilization in lower-extremity total joint arthroplasty. An analysis of 182,146 consecutive patients who underwent primary total joint arthroplasty was performed with use of data entered into the Perspective database by 3421 physicians from 312 hospitals over a two-year period. Adherence to evidence-based processes of care was defined by administration of appropriate perioperative antibiotic prophylaxis, beta-blockade, and venous thromboembolism prophylaxis. Patient outcomes included mortality, length of hospital stay, discharge disposition, surgical complications, readmissions, and reoperations within the first thirty days after discharge. Hierarchical models were used to estimate the effects of hospital and surgeon procedure volume and process standardization on individual and combined surgical outcomes and length of stay. After adjustment in multivariate models, higher surgeon volume was associated with lower risk of complications, lower rates of readmission and reoperation, shorter length of hospital stay, and higher likelihood of being discharged home. Higher hospital volume was associated with lower risk of mortality, lower risk of readmission, and higher likelihood of being discharged home. The impact of process standardization was substantial; maximizing adherence to evidence-based processes of care resulted in improved clinical outcomes and shorter length of hospital stay, independent of hospital or surgeon procedure volume. Although surgeon and hospital procedure volumes are unquestionably correlated with patient outcomes in total joint arthroplasty, process standardization is also strongly associated with improved quality and efficiency of care. The exact relationship between individual processes of care and patient outcomes has not been established; however, the findings suggest that process standardization could help providers optimize quality and efficiency in total joint arthroplasty, independent of hospital or surgeon volume.

Zhang et al (2010) completed a study to update evidence for available therapies in the treatment of hip and knee osteoarthritis (OA) and to examine whether research evidence has changed from 31 January 2006 to 31 January 2009. A systematic literature search was undertaken using MEDLINE, EMBASE, CINAHL, AMED, Science Citation Index and the Cochrane Library. The quality of studies was assessed. Effect sizes (ESs) and numbers needed to treat were calculated for efficacy. Relative risks, hazard ratios (HRs) or odds ratios were estimated for side effects. Publication bias and heterogeneity were examined. Sensitivity analysis was undertaken to compare the evidence pooled in different years and different qualities. Cumulative meta-analysis was used to examine the stability of evidence. Sixty-four systematic reviews, 266 randomized controlled trials (RCTs) and 21 new economic evaluations (EEs) were published between 2006 and 2009. Of 51 treatment modalities, new data on

efficacy have been published for more than half (26/39, 67%) of those for which research evidence was available in 2006. Among non-pharmacological therapies, ES for pain relief was unchanged for self-management, education, exercise and acupuncture. However, with new evidence the ES for pain relief for weight reduction reached statistical significance, increasing from 0.13 [95% confidence interval (CI) -0.12, 0.36] in 2006 to 0.20 (95% CI: 0.00, 0.39) in 2009. By contrast, the ES for electromagnetic therapy which was large in 2006 (ES=0.77, 95% CI: 0.36, 1.17) was no longer significant (ES=0.16, 95% CI: -0.08, 0.39). Among pharmacological therapies, the cumulative evidence for the benefits and harms of oral and topical non-steroidal anti-inflammatory drugs, diacerhein and intra-articular (IA) corticosteroid was not greatly changed. The ES for pain relief with acetaminophen diminished numerically, but not significantly, from 0.21 (0.02, 0.41) to 0.14 (0.05, 0.22) and was no longer significant when analysis was restricted to high quality trials (ES=0.10, 95% CI: -0.0, 0.23). New evidence for increased risks of hospitalization due to perforation, peptic ulceration and bleeding with acetaminophen greater than 3g/day have been published (HR=1.20, 95% CI: 1.03, 1.40). ES for pain relief from IA hyaluronic acid, glucosamine sulphate, chondroitin sulphate and avocado soybean unsponifiables also diminished and there was greater heterogeneity of outcomes and more evidence of publication bias. Among surgical treatments further negative RCTs of lavage/debridement were published and the pooled results demonstrated that benefits from this modality of therapy were no greater than those obtained from placebo. Publication of a large amount of new research evidence has resulted in changes in the calculated risk-benefit ratio for some treatments for OA. Regular updating of research evidence can help to guide best clinical practice.

> Escobar et al (2003) performed a study to develop and test an appropriateness of indications tool for total knee replacement (TKR) in patients with osteoarthritis. Criteria were developed using a modified Delphi panel judgment. Another panel rated the same indications, and the results were compared with the main panel. Test-retest of the main panel was performed. Regression models were used to assess the contribution of each algorithm variable. A classification tree was developed. The procedure was considered appropriate in 167 (26.8%) scenarios, and there was agreement on 112 (67.1%) of them. When the rates of the main panel were compared with those of a second panel, the result was a kappa statistic of 0.75. The test-retest kappa for the main panel was 0.78. Neither in the first case nor in the second was there an instance in which a scenario classified as appropriate shifted to inappropriate or vice versa. The regression models showed that symptomatology and radiology were the variables that explained most of the variability of appropriateness as determined by panelists. In the classification tree performed, the probability of misclassification was 3.8% with 150 scenarios, of the 156 analyzed and classified correctly. The previous parameters tested showed acceptable results for an evaluation tool. These results support the use of this algorithm as an aid in formulating clinical practice guidelines and to promote the appropriateness of TKR.

Summary of Evidence

Total knee arthroplasty (TKA), also known as Total Knee Replacement (TKR), for advanced medial, lateral, or patellofemoral compartment joint disease [e.g., osteoarthritis (OA)], is supported with sufficient clinical evidence in the published scientific literature as safe and effective in relieving pain and improving joint function and mobility in patients who have failed nonsurgical medical management. Despite the potential benefits, TKA it is an elective procedure and should only be considered after extensive discussion of the risks, benefits, and alternatives. Failure of a total knee replacement may require revision, which has been successful for many individuals. There is insufficient evidence to support the safety, efficacy, and improved long-term outcomes for bicompartmental, bi-unicompartmental (two individual compartments in the same knee) knee replacement, or focal knee joint resurfacing (e.g., HemiCAP™, UniCAP™). The clinical benefit of a minimally invasive surgical approach for total knee replacement has not yet been established in the medical literature. Further clinical studies are required to document long-term effectiveness, durability and improvement in functional outcomes with use of these technologies.

Ongoing and Unpublished Clinical Trials

Scientists are studying replacement joints to find out which are best to improve movement and flexibility. They are also looking at new joint materials and other ways to improve surgery. For example, researchers are looking for ways to reduce the body's inflammatory response to the artificial joint components, and are trying to learn why some types of prostheses are more successful than others. Other scientists are also trying to find out why some people who need surgery don't choose it. They want to know what things make a difference in choosing treatment, in recovery, and in well-being.

An online search of www.ClinicalTrials.gov identified the following studies in patients who have met the medically necessary criteria for a Total Knee Arthroplasty:

- NCT01705886 is a study to document and compare the surgical and after surgery costs, recovery time, and outcomes of two procedure types:
  - Robotic assisted surgery replacing one compartment of the knee
  - Manual (robot is not used) surgery replacing all three compartments of the knee (total knee replacement)

  The hypothesis is that robot assisted partial knee replacement is cost effective and provides clinical outcomes that are equivalent to a manual total knee replacement. There is an enrollment of 61 patients with an anticipated completion in January 2020.
- NCT01237860 is a manufacturer-sponsored phase 3 study of the NESS L300 Plus System. This study had an enrollment of 45 and is listed as completed. No results have been posted.

Also identified were a number of studies on functional NMES for treatment of patients with acute and chronic stroke conditions. These trials primarily focus on rehabilitation and strengthening.

Supplemental Information

Practice Guidelines and Position Statements

Guideline recommendations for the treatment of OA of the knee, according to the American Academy of Orthopaedic Surgeons (AAOS) clinical practice guideline, are shown in Table 1. The following is the AAOS summary of recommendations:

> "This summary of the AAOS clinical practice guideline, "Treatment of Osteoarthritis of the Knee" contains a list of the evidence based treatment recommendations and includes only less invasive alternatives to knee replacement. Discussion of how and why each recommendation was developed and the evidence report are contained in the full guideline at www.aaos.org/guidelines. Readers are urged to consult the full guideline for the comprehensive evaluation of the available scientific studies. The recommendations were established using methods of evidence-based medicine that rigorously control for bias, enhance transparency, and promote reproducibility.
>
> The summary of recommendations is not intended to stand alone. Medical care should always be based on a physician's expert judgment and the patient's circumstances, values, preferences and rights. For treatment procedures to provide benefit, mutual collaboration with shared decision-making between patient and physician/allied healthcare provider is essential."

Table 1: AAOS Evidence Based Treatment Recommendations

Recommendation	Strength of Recommendation	Description
Conservative Treatments		
1: We recommend that patients with symptomatic osteoarthritis of the knee participate in self-management programs, strengthening, low-impact	Strong	Evidence is based on two or more "High" strength studies with consistent findings for recommending for or against the intervention. A Strong recommendation means that the benefits

Recommendation	Strength of Recommendation	Description
aerobic exercises, and neuromuscular education; and engage in physical activity consistent with national guidelines.		of the recommended approach clearly exceed the potential harm and/or that the quality of the supporting evidence is high.
2: We suggest weight loss for patients with symptomatic osteoarthritis of the knee and a BMI ≥ 25.	Moderate	Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention. A Moderate recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the quality/applicability of the supporting evidence is not as strong.
3A: We cannot recommend using acupuncture in patients with symptomatic osteoarthritis of the knee.	Strong	Evidence is based on two or more "High" strength studies with consistent findings for recommending for or against the intervention. A Strong recommendation means that the quality of the supporting evidence is high. A harms analysis on this recommendation was not performed.
3B: We are unable to recommend for or against the use of physical agents (including electrotherapeutic modalities) in patients with symptomatic osteoarthritis of the knee.	Inconclusive	Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An Inconclusive recommendation means that there is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.
3C: We are unable to recommend for or against manual therapy in patients with symptomatic osteoarthritis of the knee.	Inconclusive	Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An Inconclusive recommendation means that there is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.
4: We are unable to recommend for or against the use of a valgus directing force brace (medial compartment unloader) for patients with symptomatic osteoarthritis of the knee.	Inconclusive	Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An Inconclusive recommendation means that there is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.
5: We cannot suggest that lateral wedge insoles be used for patients with symptomatic medial compartment osteoarthritis of the knee.	Moderate	Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention. A Moderate recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the quality/applicability of the supporting evidence is not as strong.
6: We cannot recommend using glucosamine and chondroitin for patients with symptomatic osteoarthritis of the knee.	Strong	Evidence is based on two or more "High" strength studies with consistent findings for recommending for or against the intervention. A Strong recommendation means that the quality of the supporting evidence is high. A harms analysis on this recommendation was not performed.

Recommendation	Strength of Recommendation	Description
Pharmacologic Treatments		
7A: We recommend nonsteroidal anti-inflammatory drugs (NSAIDs; oral or topical) or Tramadol for patients with symptomatic osteoarthritis of the knee.	Strong	Evidence is based on two or more "High" strength studies with consistent findings for recommending for or against the intervention. A Strong recommendation means that the quality of the supporting evidence is high. A harms analysis on this recommendation was not performed.
7B: We are unable to recommend for or against the use of acetaminophen, opioids, or pain patches for patients with symptomatic osteoarthritis of the knee.	Inconclusive	Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An Inconclusive recommendation means that there is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.
Procedural Treatments		
8: We are unable to recommend for or against the use of intraarticular (IA) corticosteroids for patients with symptomatic osteoarthritis of the knee.	Inconclusive	Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An Inconclusive recommendation means that there is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.
9: We cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee.	Strong	Evidence is based on two or more "High" strength studies with consistent findings for recommending for or against the intervention. A Strong recommendation means that the quality of the supporting evidence is high. A harms analysis on this recommendation was not performed.
10: We are unable to recommend for or against growth factor injections and/or platelet rich plasma for patients with symptomatic osteoarthritis of the knee.	Inconclusive	Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An Inconclusive recommendation means that there is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.
11: We cannot *suggest* that the practitioner use needle lavage for patients with symptomatic osteoarthritis of the knee.	Moderate	Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention. A Moderate recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the quality/applicability of the supporting evidence is not as strong.
Surgical Treatments		
12: We cannot recommend performing arthroscopy with lavage and/or debridement in patients with a primary diagnosis of symptomatic osteoarthritis of the knee.	Strong	Evidence is based on two or more "High" strength studies with consistent findings for recommending for or against the intervention. A Strong recommendation means that the quality of the supporting evidence is high. A harms analysis on this recommendation was not performed.
13: We are unable to recommend for or against arthroscopic partial meniscectomy in patients with	Inconclusive	Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention.

Recommendation	Strength of Recommendation	Description
osteoarthritis of the knee with a torn meniscus.		An Inconclusive recommendation means that there is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.
14: The practitioner might perform a valgus producing proximal tibial osteotomy in patients with symptomatic medial compartment osteoarthritis of the knee.	Limited	Evidence from two or more "Low" strength studies with consistent findings, or evidence from a single Moderate quality study recommending for or against the intervention or diagnostic. A Limited recommendation means that the quality of the supporting evidence is unconvincing, or that well-conducted studies show little clear advantage to one approach over another.
15: In the absence of reliable evidence, it is the opinion of the work group not to use the free-floating (un-fixed) interpositional device in patients with symptomatic medial compartment osteoarthritis of the knee.	Consensus	The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. A Consensus recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria of the guideline's systematic review.

Medicare National Coverage

Medicare does not have a National Coverage Determination, but does have a Local Coverage Determination (LCD) for Total Knee Arthroplasty (L36575) effective December 1, 2019.

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50. National Center for Biotechnology Information. A Meta-analysis of Functional Outcomes in Patient-Specific Instrumented Knee Arthroplasty, 2016. Accessed November 6, 2023 from https://www.ncbi.nlm.nih.gov/pubmed/27907935.

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical records indicating pain and functional disability that interferes with ADLs
  - Documentation of limited range of motion
  - Reason for surgical intervention
  - Treatment plan (i.e., surgical intervention)
- Prior conservative treatments, duration, and response
- Past and present diagnostic testing and results
- Pertinent past procedural and surgical history
- Radiology report(s) (i.e., MRI, CT) used to make surgical decision

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	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
	27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/01/2016	Custom Policy
07/01/2016	Policy revision without position change
12/01/2017	Policy revision without position change
09/01/2018	Policy revision without position change
10/01/2019	Policy revision without position change
04/01/2020	Administrative update
06/01/2020	Annual review. Policy statement and literature updated.
11/01/2020	Administrative update. Policy statement and guidelines updated.
06/01/2021	Annual review. No change to policy statement.
07/01/2022	Annual review. No change to policy statement.
09/01/2022	Administrative update. Policy statement updated.
12/01/2022	Annual review. Policy statement, guidelines and literature updated.
12/01/2023	Annual review. Policy statement and guidelines updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue

Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	**AFTER** Blue font: Verbiage Changes/Additions
Knee Arthroplasty for Adults BSC7.10 **Policy Statement:** I. Knee arthroplasty may be considered **medically necessary** when **all** of the following criteria have been met: A. The reason for the arthroplasty is osteoarthritis (OA), rheumatoid arthritis, osteonecrosis, or post-traumatic arthritis of the knee joint B. It is NOT for bicompartmental knee replacement, including bi-unicompartmental (two individual compartments in the same knee) C. It is NOT for a customized knee replacement, including **all** of the following: 1. It does NOT use customized knee implant 2. It does NOT use a "Gender specific" implant D. It does NOT use focal resurfacing of a single knee joint defect (e.g., HemiCAP™, UniCAP™) E. It does NOT use minimally invasive approaches to knee arthroplasty F. The patient has **one or more** of the following conditions: 1. Degenerative joint disease when **all** of the following conditions exist: a. Documentation of unsuccessful conservative therapy (non-surgical medical management), or documentation of rationale if conservative therapy is considered inappropriate b. Documentation of limited range of motion, antalgic gait, and pain in knee joint with passive range of motion on physical examination c. Radiographic evidence of severe osteoarthritis as evidenced by **either** of the following: i. The presence of definite joint space narrowing with sclerosis and possible deformity of bone ends	**Knee Arthroplasty for Adults BSC7.10** **Policy Statement:** I. Knee arthroplasty may be considered **medically necessary** when **all** of the following criteria have been met: A. The reason for the arthroplasty is osteoarthritis (OA), rheumatoid arthritis, osteonecrosis, or post-traumatic arthritis of the knee joint B. It is NOT for bicompartmental knee replacement, including bi-unicompartmental (two individual compartments in the same knee) C. It is NOT for a customized knee replacement, including **all** of the following: 1. It does NOT use customized knee implant 2. It does NOT use a "Gender specific" implant D. It does NOT use focal resurfacing of a single knee joint defect (e.g., HemiCAP™, UniCAP™) E. It does NOT use minimally invasive approaches to knee arthroplasty F. The individual has **one or more** of the following conditions: 1. Degenerative joint disease when **all** of the following conditions exist: a. Documentation of unsuccessful conservative therapy (non-surgical medical management), or documentation of rationale if conservative therapy is considered inappropriate b. Documentation of limited range of motion, antalgic gait, and pain in knee joint with passive range of motion on physical examination c. Radiographic evidence of severe osteoarthritis as evidenced by **either** of the following: i. The presence of definite joint space narrowing with sclerosis and possible deformity of bone ends

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	**AFTER** Blue font: Verbiage Changes/Additions
ii. The presence of large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of the proximal tibia or distal femur 2. Distal femur fracture repair in a patient with osteoporosis 3. Failure of a previous proximal tibial or distal femoral osteotomy 4. Hemophilic arthroplasty 5. Limb salvage for malignancy 6. Posttraumatic knee joint destruction 7. Replacement or revision of previous arthroplasty as indicated by **one or more** of the following conditions: a. Disabling pain b. Functional disability c. Progressive and substantial bone loss d. Fracture of patella e. Dislocation of patella f. Aseptic component instability g. Infection h. Periprosthetic fracture II. Knee arthroplasty is considered **investigational** if the patient's situation does not meet the criteria above.	ii. The presence of large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of the proximal tibia or distal femur 2. Distal femur fracture repair in a individual with osteoporosis 3. Failure of a previous proximal tibial or distal femoral osteotomy 4. Hemophilic arthroplasty 5. Limb salvage for malignancy 6. Posttraumatic knee joint destruction 7. Replacement or revision of previous arthroplasty as indicated by **one or more** of the following conditions: a. Disabling pain b. Functional disability c. Progressive and substantial bone loss d. Fracture of patella e. Dislocation of patella f. Aseptic component instability g. Infection h. Periprosthetic fracture II. Knee arthroplasty is considered **investigational** if the individual's situation does not meet the criteria above.