I. Aetna considers a Food and Drug Administration (FDA) approved total knee arthroplasty (TKA) prosthesis medically necessary for adult members when the following criteria are met:

A. Member has advanced joint disease demonstrated by:

1. Pain and functional disability that interferes with ADLs from injury due to osteoarthritis, rheumatoid arthritis, avascular necrosis, or post-traumatic arthritis of the knee joint; and
2. Limited range of motion, crepitus, or effusion or swelling of knee joint on physical examination; and
3. Radiographic evidence of severe osteoarthritis (as evidence by two or more of the following: subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, or joint space narrowing)
of knee joint, or avascular necrosis (osteonecrosis) of tibial or femoral condyle, or rheumatoid arthritis (joint space narrowing); and

4. History of unsuccessful conservative therapy (non-surgical medical management) that is clearly addressed in the medical record (see note). Conservative therapy may be inappropriate for severe osteoarthritis with bone-on-bone articulation and severe angular deformity, or avascular necrosis with collapse of tibial or femoral condyle. If conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable; or

B. Failure of a previous osteotomy with pain interfering with ADLs; or

C. Distal femur or proximal tibia fracture, malunion or nonunion by imaging with pain interfering with ADLs; or

D. Malignancy of the distal femur, proximal tibia, knee joint or adjacent soft tissues by imaging; or

E. Failure of previous unicompartmental knee replacement with pain interfering with ADLs.

**Note:** Members with osteoarthritis, traumatic arthritis, or avascular necrosis should have at least 12 weeks of nonsurgical treatment documented in the medical record (at least 24 weeks for persons with a relative contraindication), including all of the following, unless contraindicated:

1. Anti-inflammatory medications or analgesics; and

2. Flexibility and muscle strengthening exercises, and

3. Activity modification; and

4. Supervised physical therapy [Activities of daily living (ADLs) diminished despite completing a plan of care]; and

5. Assistive device use (required for persons with relative contraindications* to joint replacement, optional for others), and

6. Therapeutic injections into the knee (required for persons with relative contraindications* to joint replacement, optional for others).
* Relative contraindications to joint replacement include the following: morbid obesity (BMI greater than 40), age less than 50 years). Members with relative contraindications should exhaust all nonsurgical treatment options.

F. Total joint replacement is considered not medically necessary in persons with any of the following absolute contraindications:

1. Active infection of the joint or active systemic bacteremia that has not been totally eradicated; or
2. Active skin infection (exception recurrent cutaneous staph infections) or open wound within the planned surgical site of the knee; or
3. Rapidly progressive neurological disease; or
4. Allergy to components of the implant (e.g., cobalt, chromium or alumina).

G. For members with significant conditions or co-morbidities, the risk/benefit of total knee arthroplasty should be appropriately addressed in the medical record.

II. Aetna considers a revision or replacement of total knee arthroplasty medically necessary for the following indications when accompanied by pain and functional disability (interference with ADLs):

A. Aseptic loosening of one or more prosthetic components confirmed by imaging, or
B. Fracture of one or more components of the prosthesis or worn or dislocated plastic insert confirmed by imaging, or
C. Confirmed periprosthetic infection by gram stain and culture, or
D. Periprosthetic fracture of distal femur, proximal tibia or patella confirmed by imaging, or
E. Progressive or substantial periprosthetic bone loss confirmed by imaging, or
F. Bearing surface wear leading to symptomatic synovitis, or
G. Implant or knee malalignment (valgus/varus or flexion/extension greater than 15 degrees), or
H. Knee arthrofibrosis, or
I. Instability of dislocation of the TKA; or

J. Extensor mechanism instability; or

K. Upon individual case review, persistent knee pain of unknown etiology not responsive to a period of non-surgical care for 6 months.

And member does not have any of the following contraindications to revision surgery:

1. Persistent infection,
2. Poor bone quality,
3. Highly limited quadriceps or extensor function,
4. Poor skin coverage, and
5. Poor vascular status.

III. Aetna considers unicompartmental knee arthroplasty using Food and Drug Administration (FDA)-approved devices medically necessary for members with osteoarthritis or posttraumatic arthritis of the knee affecting only the medial or lateral compartment, and who meet the following criteria:

A. Pain and functional disability that interferes with ADLs due to osteoarthritis or post-traumatic arthritis of the knee joint; and

B. Limited range of motion, crepitus, or effusion or swelling of knee joint on physical examination: and

C. Member must have intact, stable ligaments, in particular the anterior cruciate ligament; and

D. Patient’s knee arc of motion (full extension to full flexion) is not limited to 90 degrees or less; and

E. Radiographic evidence of osteoarthritis (as evidence by two or more of the following: subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, or joint space narrowing) affecting only the medial or lateral compartment of the knee joint; and

F. History of of unsuccessful conservative therapy (non-surgical medical management) that is clearly addressed in the medical record (see Note); and

Note: Members should have at least 12 weeks of nonsurgical treatment documented in the medical record (at least 24 weeks for persons with a
relative contraindication), including all of the following, unless contraindicated:

1. Anti-inflammatory medications or analgesics; and
2. Flexibility and muscle strengthening exercises, and
3. Activity modification; and
4. Supervised physical therapy [Activities of daily living (ADLs) diminished despite completing a plan of care]; and
5. Assistive device use (required for persons with relative contraindications*: to joint replacement, optional for others), and
6. Therapeutic injections into the knee (required for persons with relative contraindications*: to joint replacement, optional for others).

* Relative contraindications to unicompartmental knee arthroplasty include the following: morbid obesity (BMI greater than 40), age less than 50 years). Members with relative contraindications should exhaust all nonsurgical treatment options.

G. Member has none of the following contraindications to unicompartmental knee arthroplasty:

1. Severe patellofemoral joint arthritis (when unicompartmental arthroplasty to be performed is medial or lateral); or
2. Previous proximal tibial osteotomy or distal femoral osteotomy; or
3. Tibial or femoral shaft deformity; or
4. Radiographic evidence of medial or lateral subluxation; or
5. Flexion contracture greater than 15º; or
6. Varus deformity greater than 15º (medial unicompartmental knee arthroplasty) or a valgus deformity greater than 20º (lateral unicompartmental knee arthroplasty); or
7. Inflammatory or crystalline arthropathy; or
8. Subchondral bone loss due to large subchondral cysts or extensive focal osteonecrosis.

H. Member has none of the following absolute contraindications to joint replacement:
1. Active infection of the joint or active systemic bacteremia that has not been totally eradicated; or
2. Active skin infection (exception recurrent cutaneous staph infections) or open wound within the planned surgical site of the knee; or
3. Rapidly progressive neurological disease; or
4. Allergy to components of the implant (e.g., cobalt, chromium or alumina).

I. For members with significant conditions or co-morbidities, the risk/benefit of unicompartmental knee arthroplasty should be appropriately addressed in the medical record.

IV. Aetna considers the UniSpacer interpositional spacer for the treatment of osteoarthritis affecting the medial compartment of the knee experimental and investigational because its effectiveness for this indication has not been established.

V. Aetna considers bimodal, staged bicompartmental, and bi-unicompartmental knee arthroplasty experimental and investigational for osteoarthritis of the knee and all other indications because their effectiveness has not been established.

VI. Aetna considers customized total knee implant experimental and investigational because its effectiveness has not been established.

VII. Aetna considers prophylactic radiation therapy following total knee arthroplasty experimental and investigational because its effectiveness has not been established.

**Note:** Intra-operative use of kinetic balance sensor for implant stability during knee replacement arthroplasty is considered incidental to the primary procedure being performed and is not eligible for separate reimbursement.

Background
Knee joint replacement is indicated for patients with significant loss or erosion of cartilage to bone accompanied by pain and limited range of motion (ROM), in patients who have had an inadequate response to conservative measures.

Guidelines indicate that unicompartmental knee arthroplasty (UKA) is indicated when only 1 compartment is affected, and total knee arthroplasty (TKA) is indicated when 2 or 3 compartments are affected.

According to available literature, UKA is contraindicated in persons with any of the following: active local or systemic infection; loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; poor bone quality; severe instability secondary to advanced loss of osteochondral structure; absence of collateral ligament integrity; or individuals with over 30 degrees of fixed varus or valgus deformity.

The UniSpacer (Sulzer Orthopedics, Austin, TX) is a metallic interpositional spacer for arthritis affecting primarily the medial compartment of the knee. The device is a U-shaped metallic shim, designed to be implanted in the knee joint following removal of any damaged cartilage. The UniSpacer has been used for the treatment of isolated, moderate degeneration of the medial compartment (Grade III to IV chondromalacia) with no more than minimal degeneration (Grade I to II chondromalacia, no loss of joint space) in the lateral condyle or patellofemoral compartment. The UniSpacer is intended to restore the stability and alignment of the knee and relieve pain, thereby delaying or avoiding the need for total knee replacement (TKR).

The manufacturer states that an advantage of the UniSpacer over TKR is that the procedure to implant the UniSpacer involves no cutting of the patient's bone and no cementing of the implant in the knee. A small incision is required before the implant can be inserted. The UniSpacer is designed to center itself in the knee, so that no alteration of the surrounding bone or soft tissues is required for implantation. The manufacturer states that surgery to implant the UniSpacer takes about 1 hour to complete, and the patient usually is only required to stay over-night after the procedure, instead of the 3 to 4 days required by a TKR.
According to the manufacturer's website, approximately 90 patients have been implanted with the UniSpacer. The manufacturer's website states that outcomes so far have been "excellent", although the follow-up on these patients is relatively short (the longest being approximately 1.5 years). The manufacturer's website states that there have been no revisions or complications in any of the cases.

The manufacturer's website states that the UniSpacer is targeted for younger patients who have unicompartmental arthritis involving the medial compartment of their knee. The majority of the patients who have been implanted with the UniSpacer are under 65 and, therefore, are not yet ideal candidates for TKR.

According to the manufacturer's website, the UniSpacer is currently only available through a small group of specially trained surgeons who are participating in an assessment research project of the device. However, there is insufficient published evidence of the effectiveness and durability of this device. Because of the lack of adequate prospective studies in the peer-reviewed published medical literature, the clinical value of UniSpacer has yet to be established.

Scott (2003) stated that the eventual role of the UniSpacer in arthroplasty currently is uncertain. There are no published reports of its effectiveness. Its indication should be similar to those for McKeever arthroplasty. A patient with unicompartmental osteoarthritis in whom an osteotomy is contraindicated but is considered too young, heavy, or active for a metal-to-plastic arthroplasty is ideal. Less than 1% of patients with osteoarthritis should be appropriate candidates.
Scott (2003) stated that procedure is technically demanding and sensitive, making its widespread success unlikely.

A technology assessment by the California Technology Assessment Forum (Tice, 2003) concluded that the UniSpacer did not meet CTAF’s assessment criteria. The assessment concluded that “[s]urgical placement of knee joint spacer devices requires evaluation in controlled trials in order to assess the efficacy and safety of the procedure before its widespread adoption can be advocated.”

The Washington State Department of Labor and Industries (2005) has stated that it does not cover the UniSpacer device because of an absence of clinical data and published literature regarding its safety and efficacy.
Guidance from the National Institute for Health and Clinical Excellence (NICE, 2009) concludes: "Current evidence on the safety and efficacy of individually magnetic resonance imaging (MRI)-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research studies".

A technology assessment of TKA prepared for the Washington State Health Care Authority (Dettori et al, 2010) identified only 1 randomized controlled trial (RCT) that reported on a comparison between UKA and standard TKA. Regarding knee function, the report found that, in the 1 RCT comparing UKA with TKA, the mean Bristol Knee Score was similar between the UKA and TKA groups 5 and 15 years following surgery: 91.1 (range of 32 to 100) and 92 (range of 32 to 100) compared with 86.7 (range of 48 to 98) and 88 (range of 48 to 98). The report observed that a larger percentage of the UKA group reported excellent Bristol scores at 5- and 15-year follow-up (76 % and 71 %, respectively) than in the TKA group (57 % and 53 %, respectively), although this did not reach statistical significance). Regarding failure rates, the report stated that statistically significant differences in failure rate defined as revision or a Bristol Knee Score less than 60 were not reported; however, at 15-year follow-up, 17 % of the UKA group and 24 % of the TKA group had experienced failure. The report found no statistically significant differences in revision rates between UKA and TKA at 15-year follow-up. Thirteen percent of the UKA group and 16 % of the TKA group had experienced revision. The report also found no statistically significant differences in survival rate at 15-year follow-up: 89.8 % (95 % confidence interval [CI]: 74.3 to 100) for the UKA group and 78.7 % (95 % CI: 56.2 to 100) for the TKA group (p > 0.05). The report also found knee pain, function and revision rates were comparable between the 2 treatment groups in 14 cohort studies reporting over a variety of follow-up times. The report identified 2 RCTs providing data on the efficacy of UKA compared with TKA; in these studies, there were no significant differences in knee pain, knee function, failure or revision, or ROM between the groups from 1 year to 10 years of follow-up. Regarding safety, no deaths and few complications were reported in 1 RCT and 9 cohort studies. No statistical significance between UKA and TKA was reported in the number of patients experiencing venous thromboembolism, the knees requiring manipulation under anesthesia or the number of knees having delayed wound healing. Three studies reported complications after treatment with UKA or high tibial osteotomy (HTO); there were no differences between groups.
Bailie and colleagues (2008) reported the findings of a prospective study of 18 patients treated with the Unispacer. The mean age of the patients was 49 years (40 to 57). A total of 8 patients (44 %) required revision within 2 years. In 2 patients, revision to a larger spacer was required, and in 6 conversion to either a UKA or TKR was needed. At the most recent review 12 patients (66.7 %) had a Unispacer remaining in-situ. The mean modified visual analog score for these patients at a mean follow-up of 19 months (12 to 26) was 3.0 (0 to 11.5). The mean pain level was 30 % that of the mean pre-operative level of 10. The early clinical results using this device have been disappointing. This study demonstrated that use of the Unispacer in isolated medial compartment osteoarthritis is associated with a high rate of revision surgery and provides unpredictable relief of pain.

Clarius et al (2010) assessed clinical and radiological results of the UniSpacer, whether alignment correction can be achieved by UniSpacer arthroplasty and alignment change in the first 5 post-operative years. Antero-posterior long leg stance radiographs of 20 legs were digitally analysed to assess alignment change: 2 relevant angles and the deviation of the mechanical axis of the leg were analysed before and after surgery. Additionally, the change of the post-operative alignment was determined at 1 and 5 years post-operatively. Analysing the mechanical tibio-femoral angle, a significant leg axis correction was achieved, with a mean valgus change of 4.7 +/- 1.9 degrees ; a varus change occurred in the first post-operative year, while there was no significant further change of alignment seen 5 years after surgery. The UniSpacer corrects mal-alignment in patients with medial gonarthrosis; however, a likely post-operative change in alignment due to implant adaptation to the joint must be considered before implantation. The authors concluded that these findings show that good clinical and functional results can be achieved after UniSpacer arthroplasty. However, 4 of 19 knees had to be revised to a TKA or UKA due to persistent pain, which is an unacceptably high revision rate when looking at the alternative treatment options of medial osteoarthritis of the knee.

Kock et al (2011) examined if an interpositional knee implant based on magnetic resonance imaging (MRI) data can be an alternative treatment option to the established procedures of high tibial osteotomy and UKA. From June 2004 to May 2008, a total of 33 patients suffering from unicompartmental knee arthritis received a patient-specific interpositional implant (31 medial and 2 lateral) within a single-arm trial. The mean follow-up time was 26.6 months (range of 1 to 48 months) and the mean age of the patients was 54.5 years (range of 39 to 65 years). In addition
to the clinical results the Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) function scale and the Knee Society scores were measured. A descriptive data analysis, a variance analysis for repeated measurements and a determination of significance level were carried out. The 2 to 4 year results showed a significant improvement in the WOMAC function scale as well as the Knee Society scores. The knee function after 2 years was comparable to the pre-operative situation with an extension to flexion of 0/2/130°. The dislocation rate was 6% and the overall revision rate 21%. The authors concluded that despite acceptable functional results a significant pain relief, a complete preservation of bone and a lower rate of dislocations compared to the off-the-shelf Unispacer implant there were only limited indications for the customized interpositional knee implant with respect to the given contraindications due to the high 2-year revision rate.

Catier et al (2011) noted that a new concept has been recently developed for use in the treatment of isolated medial tibio-femoral osteoarthritis: the Unispacer implant. This mobile interpositional, self-centering implant replicates the meniscal shape. This mini-invasive device does not require bone cuts or component fixation. The implant trajectory is guided by the medial condyle. These investigators hypothesized that the Unispacer knee implant enhances knee function in the treatment of isolated tibio-femoral osteoarthritis graded 2 and 3 according to Ahlbäck radiographic evaluation scale. This prospective study involved 17 Unispacer knee systems implanted in 16 patients between April 2003 and March 2009 within the frame of a clinical research project. Patients were clinically (IKS score) and radiographically evaluated during a mean follow-up period of 40 months. A total of 9 patients (10 implants) had a IKS score greater than 160. The mean overall knee score at re-assessment, including failures, increased from 51 points pre-operatively to 78 points post-operatively. The mean overall Knee Society Function score increased from 55 pre-operatively to 75/100 post-operatively. The reported complication rate was 35% (pain or implant instability); 1/3 of the failures were not technique- or implant-related but rather induced by the use of an inappropriate width in the frontal plane. The authors concluded that good results regarding pain relief and function are reported when using a mobile implant with no peripheral overhang that could be responsible for medial capsulo-ligamentous impingement. The Unispacer has 3 theoretical advantages: (i) no bone resection, (ii) no implant fixation, and (iii) no polyethylene wear debris. On the basis of its uncertain clinical results and high revision rate (6 cases out of
these researchers do not recommend this system despite the expected improvements on this range of implants.

It has been suggested that bicompartmental knee replacement may be indicated for individuals with osteoarthritis limited to the medial and patello-femoral compartments. Bicompartmental knee replacement replaces only the inside (medial) joint and knee-cap joint (patello-femoral) joint. It does not re-surface the outside (lateral) part of the knee and allows for the anterior cruciate ligament (ACL) and posterior cruciate ligament to be retained.

A systematic evidence review of TKA prepared for the Washington State Health Care Authority (Dettori et al, 2010) found 2 registry studies providing comparative data between bicompartmental and standard tricompartmental knee arthroplasty. These 2 registry studies reported low revision rates in both the bi- and tri-compartmental groups: 3.2 % and 2.8 %, respectively, at 2 to 4 years follow-up and 1.5 % and 1.6 %, respectively, at 2 years follow-up. No significant differences in overall revision rates between the 2 treatment groups were reported by either study. Complications were not reported for 2 registry studies comparing bi- and tri-compartmental TKA.

In a meta-analysis, Callahan et al (1995) summarized the literature describing patient outcomes following unicompartmental as well as bicompartmental knee arthroplasties. Original studies were included 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. A total of 46 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 post-operative 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 pre-operative 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 post-operative global rating scale score was 78.3. The overall complication
rate was 30% and the revision rate was 7.2%. Although bicompartimental studies reported lower mean post-operative global rating scale scores, these studies tended to enroll patients with worse pre-operative knee rating scores. Recent improvements in patient outcomes following UKA appear to be due, at least partially, to changes in patient selection criteria. Patient outcomes appear to be worse for bicompartimental 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.

Rolston et al (2007) stated that in the past, treatment of knee osteoarthritis has been limited to UKA or TKA. Neither option is well-suited for the active patient with mid-stage osteoarthritis of the medial and patello-femoral compartments. Now an alternative treatment is available that targets the diseased area without sacrifice of normal bone or both the cruciate ligaments. Minimally invasive surgical techniques are easily used, which reduces tissue trauma and results in a quicker recovery than TKA. Bicompartmental replacement offers decreased pain, stability through normal ligament structure, and the retention of normal bone for patients with medial and patello-femoral osteoarthritis.

Bi-unicompartmental knee arthroplasty refers to UKA performed in the contralateral compartment of a knee previously treated with a UKA.

A systematic evidence review of TKA prepared for the Washington State Health Care Authority (Dettori et al, 2010) reported on studies comparing bi-unicompartmental knee arthroplasty (bi-UKA) and standard TKA. The report found 1 small retrospective cohort study comparing bi-UKA with TKA. No difference was found in functional scores at a minimum of 4 years of follow-up, and no revisions were recorded in either group. No cases of radiological loosening or infection were seen in either the bi-UKA or TKA groups. Two cases (9%) of intra-operative fracture of the tibial spine block occurred in the bi-UKA group but did not have any adverse effect on the outcome at last follow-up in either case.

Confalonieri and associates (2009) carried out a matched paired study between 2 groups: (i) bi-unicompartmental (Bi-UKR) and (ii) TKR for the treatment of isolated bicompartimental tibio-femoral knee arthritis with an asymptomatic patello-femoral joint. A total of 22 patients with bicompartimental tibio-femoral knee arthritis, who underwent Bi-UKR were included in the study (group A). In all
the knees the arthritic changes were graded according to the classification of Alback. All patients had an asymptomatic patello-femoral joint. All patients had a varus deformity lower than 8 degrees, a body-mass index lower than 34, no clinical evidence of ACL laxity or flexion deformity and a pre-operative range of motion of at least 110 degrees. At a minimum follow-up of 48 months, every single patient in group A was matched with a patient who had undergone a computer-assisted TKR (group B). In the Bi-UKR group, in 2 cases these researchers registered intra-operatively the avulsion of the treated tibial spines, requiring intra-operative internal fixation and without adverse effects on the final outcome. Statistical analysis of the results was performed. At a minimum follow-up of 48 months there were no statistical significant differences in the surgical time while the hospital stay was statistically longer in TKR group. No statistically significant difference was observed for the Knee Society, Functional and GIUM scores between the 2 groups. Statistically significant better WOMAC Function and Stiffness indexes were registered for the Bi-UKR group. Total knee replacement implants were statistically better-aligned with all the implants positioned within 4 degrees of an ideal hip-knee-ankle angle of 180 degrees. The authors concluded that the findings of this 48-month follow-up study suggested that Bi-UKR is a viable option for bicompartamental tibio-femoral arthritis at least as well as TKR but maintaining a higher level of function.

Available evidence does not provide strong conclusions regarding optimal patient selection criteria as well as improved patient outcomes with bicompartamental knee arthroplasty or bi-UKA. Currently, there is no clinical practice guideline on either of these procedures. In this regard, the American Academy of Orthopaedic Surgeons' clinical guideline on osteoarthritis of the knee (2003) did not discuss the use of bicompartamental knee arthroplasty or bi-UKA as methods of treatment for osteoarthritis of the knee. Furthermore, the Osteoarthritis Research International's recommendations for the management of hip and knee osteoarthritis (Zhang et al, 2008) did not mention the use of bicompartamental or bi-UKA.

Available scientific evidence is insufficient to support the use of bicompartmental knee arthroplasty and bi-UKA as alternatives for TKR. At present, there is inadequate evidence demonstrating improved patient outcomes from either of these methods. Well-designed studies are needed to ascertain the safety and effectiveness of these approaches.
Unicompartmental knee arthroplasty is a popular treatment for unicompartmental knee arthritis. Roche and associates (2009) stated that a recently developed computer-assisted surgery/robotic system has the potential to improve alignment in and results of UKA. Pearle et al (2009) stated that indications for UKA include mechanical axis of less than 10 degrees varus and less than 5 degrees valgus, intact ACL, and absence of femoro-tibial subluxation. Appropriately selected patients can expect UKA to last at least 10 years. Failures in UKA are not common and involve technical errors that are thought to be corrected with use of newly developed robotic technology such as the MAKO robotic arm system (MAKOplasty). The surgeon using this technology may be able to arrive at a set target, enhance surgical precision, and avoid outliers. However, whether improved precision will result in improved long-term clinical outcome remains a subject of research.

Sinha (2009) reported that the early outcomes of UKA performed with a robotically assisted navigation system have been favorable. The surgical technique enhances accuracy of bone preparation and component positioning. Technical errors of the system have been minimal. The surgeon's learning curve is not adversely affected. Early patient outcomes are excellent and complications minimal. The authors noted that further follow-up studies will help to determine whether these early outcomes are sustained over time.

Lonner (2009) noted that modular biconartmental arthroplasty is an emerging knee-resurfacing approach that provides a conservative alternative to TKA. Isolated bicompartamental arthritis involving the medial or lateral and patello-femoral compartments, but with no significant deformity or bone deficiency, preserved motion, and intact cruciate ligaments, can be effectively managed with this treatment method. For the many young and active patients with isolated bicompartamental arthritis, given the potential durability of the procedure and the prosthesis, it is appropriate to use an approach that is more conservative than TKA. Robotic arm assistance for modular bicompartamental arthroplasty optimizes component position and alignment, which may improve system performance and long-term durability. In addition, a percentage of patients who undergo isolated unicompartmental or patello-femoral arthroplasty may later develop progressive arthritis in an unresurfaced compartment. Their cases may be effectively managed with a staged modular approach to resurfacing the degenerating compartment, but additional study is needed.
In a pilot study, Lonner et al (2010) compared the post-operative radiographical alignment of the tibial component with the pre-operatively planned position in 31 knees in 31 consecutive patients undergoing UKA using robotic arm-assisted bone preparation and in 27 consecutive patients who underwent unilateral UKA using conventional manual instrumentation to determine the error of bone preparation and variance with each technique. Radiographically, the root mean square error of the posterior tibial slope was 3.1 degrees when using manual techniques compared with 1.9 degrees when using robotic arm assistance for bone preparation. In addition, the variance using manual instruments was 2.6 times greater than the robotically guided procedures. In the coronal plane, the average error was 2.7 degrees +/- 2.1 degrees more varus of the tibial component relative to the mechanical axis of the tibia using manual instruments compared with 0.2 degrees +/- 1.8 degrees with robotic technology, and the varus-valgus root mean square error was 3.4 degrees manually compared with 1.8 degrees robotically. The authors concluded that further study will be necessary to determine whether a reduction in alignment errors of these magnitudes will ultimately influence implant function or survival.

Paratte and associates (2010) stated that recent literature suggests patients achieve substantial short-term functional improvement after combined bicompartmental implants but longer-term durability has not been documented. These investigators examined if (i) bicompartmental arthroplasty (either combined medial unicompartmental UKA and femoro-patellar arthroplasty (PFA) or medial UKA/PFA, or combined medial and lateral UKA or bicompartmental UKA) reliably improved Knee Society pain and function scores; (ii) bicompartmental arthroplasty was durable (survivorship, radiographical loosening, or symptomatic disease progression); (iii) durable alignment can be achieved; and (iv) the arthritis would progress in the unresurfaced compartment. These researchers retrospectively reviewed 84 patients (100 knees) with bicompartmental UKA and 71 patients (77 knees) with medial UKA/PFA. Clinical and radiographical evaluations were performed at a minimum follow-up of 5 years (mean of 12 years; range of 5 to 23 years). Bicompartmental arthroplasty reliably alleviated pain and improved function. Prosthesis survivorship at 17 years was 78 % in the bicompartmental UKA group and 54 % in the medial UKA/PFA group. The high revision rate, compared with TKA, may be related to several factors such as implant design, patient selection, crude or absent instrumentation, or component mal-alignment, which can all contribute to the relatively high failure rate in this series.
Palumbo et al. (2011) evaluated the effectiveness of a novel bicompartmental knee arthroplasty (BKA) prosthesis for the treatment of degenerative disease affecting the medial and patello-femoral compartments. The study included 36 knees in 32 patients with a mean follow-up of 21 months. The mean Knee Society functional survey and Western Ontario McMaster Osteoarthritic Index Survey scores were 65.4 and 75.8, respectively. Thirty-one percent of patients were unsatisfied with the surgery, and 53% stated that they would not repeat the surgery. These researchers reported an overall survival rate of 86% with 1 catastrophically failed tibial baseplate. The authors concluded that this prosthesis provides inconsistent pain relief and unacceptable functional results for bicompartamental arthritis. The short-term survival of this prosthesis was unacceptably low, and therefore, these investigators no longer implant it at their institution.

Morrison and colleagues (2011) compared functional outcomes of BKA and TKA in patients with osteoarthritis (OA) of the patello-femoral and medial compartments. Eligibility criteria included bicompartamental OA with less than grade 2 OA in the lateral compartment and intact cruciate ligaments. A total of 56 patients met eligibility criteria (21 BKA, 33 TKA). Enrolled participants completed Short-Form 12 and Western Ontario and McMaster Universities Osteoarthritis Index assessments at baseline and post-operatively at 3 months, 1 year, and 2 years. In the early post-operative period, the BKA cohort had significantly less pain (p = 0.020) and better physical function (p = 0.015). These trends did not continue past 3 months. When adjusting for age, sex, body mass index, and pre-operative status, only 3-month Western Ontario and McMaster Universities Osteoarthritis Index stiffness scores significantly differed between cohorts (p = 0.048). Despite less early stiffness in the BKA cohort, a significantly higher BKA complication rate (p = 0.045) has led these investigators to recommend TKA for patients with this pattern of OA.

Lyons et al. (2012) examined if TKA would demonstrate (i) better change in clinical outcome scores from pre-operative to post-operative states and (ii) better survivorship than UKA. These researchers evaluated 4,087 patients with 5,606 TKAs and 179 patients with 279 UKAs performed between 1978 and 2009. Patients with TKA were older and heavier than patients with UKA (mean age of 68 versus 66 years; mean BMI of 32 versus 29). They compared pre-operative, latest post-operative, and change in Knee Society Clinical Rating System (KSCRS), SF-12, and WOMAC scores. Minimum follow-up was 2 years (UKA: mean of 7 years; range of 2.0 to 23 years; TKA: mean of 6.5 years; range of 2.0 to 33 years). Pre-operative outcome measure scores (WOMAC, SF-12, KSCRS) were higher in the
UKA group. Patients with UKA had higher post-operative KSCRS and SF-12 mental scores. Changes in score for all WOMAC domains were similar between groups. Total KSCRS changes in score were similar between groups, although patients with TKA had higher knee scores (49 versus 43) but lower function scores than UKA (21 versus 26). Cumulative revision rate was higher for UKA than for TKA (13% versus 7%). Kaplan-Meier survivorship at 5 and 10 years was 95% and 90%, respectively, for UKA and 98% and 95%, respectively, for TKA. The authors concluded that while patients with UKA had higher pre- and post-operative scores than patients with TKA, the changes in scores were similar in both groups and survival appeared higher in patients with TKA.

Tria (2013) stated that replacement of the patella-femoral and medial tibio-femoral joints has been performed since the 1980s. Bicompartmental replacement was modified. Two different designs were developed: one custom implant and one with multiple pre-determined 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. The author concluded that bicompartmental arthroplasty remains a questionable area of knee surgery.

Chung et al (2013) noted that 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 TKA though not previously reported in the literature. These researchers compared 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 pre-operatively, 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 2 groups, knee extensor and flexor torque, hamstring/Quadriceps ratio, position sense, and physical performance were not significantly different pre-operatively, 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. The authors concluded that although theoretically plausible, bicompartmental knee arthroplasty was not superior in knee muscle strength and physical performance at 1 year compared with TKA.

Thienpont and Price (2013) stated that studies have shown that after TKA neither normal biomechanics nor function is obtained. Selective resurfacing of diseased compartments could be a solution. These investigators presented a narrative review of the available literature on bicompartamental arthroplasty. A literature review of all peer-reviewed published articles on bicompartamental arthroplasty of the knee was performed. Bicompartamental arthroplasty is by definition the replacement of the tibio-femoral and the patella-femoral joint. It can be performed with a modular unlinked or a monolithic femoral component. Bicompartamental arthroplasty performed with modular components obtained good to excellent results at ± 10 years follow-up. Function and biomechanics are superior to TKA. Modern monolithic femoral components were reported to give early failure and high revision rates and should be avoided. The authors concluded that modular bicompartamental arthroplasty is an excellent alternative to treat bicompartamental arthritis of the knee leading to good functional results and superior biomechanics in well-selected patients. However, they stated that caution is needed since only a few peer-reviewed articles with small series and old implant designs are available on this type of arthritis treatment. Survivorship in these studies is inferior to TKA.

Furthermore, the Work Loss Data Institute’s guideline on “Knee & leg (acute & chronic)” (2013) listed bicompartamental knee replacement as one of the interventions that were considered, but are not recommended.

Luring et al (2011) stated that isolated OA of the patellofemoral joint occurs in 9 % of patients over 40 years of age and women are more often affected. Options of treatment are varied and not sufficiently justified by the literature. These investigators performed a literature research with keywords in the field of femoropatellar osteoarthritis in the relevant databases. Studies were categorized into different treatment options and analyzed. There are almost no level I studies comparing the different treatment options. In the literature there are indications that relief of pain can be achieved by conservative treatment, arthroscopic surgery, cartilage conserving surgery and isolated arthroplasty. The authors concluded that
in view of the fact that there are almost no prospective randomized controlled trials (RCTs), none of the options for treatment can be highly recommended. There is still no gold standard for the treatment of isolated patellofemoral osteoarthritis.

An assessment by the Canadian Agency for Drugs and Technologies in Health (CADTH, 2013) summarized the available evidence for patellofemoral knee implants: "Bietzel et al. reported outcomes of patello-femoral knee implants in terms of pain and knee functions. The study compared the scores of patients for these outcomes at baseline and after two years from the implant surgery. The exact scores were not reported; however, the report showed that the scores for pain and knee functions (Lyshlom score and WOMAC scores) were statistically significantly improved from baseline. The results for maximum reflection showed no statistical difference. Starks et al. reported the scores of knee functions after two years from the implantation; however, these scores were not compared to their baseline counterpart values; therefore, their significance could not be interpreted".

Davies (2013) noted that unicompartmental patellofemoral arthroplasties are uncommon however numbers are increasing and there are a variety of new prostheses available. The Femoro-Patella Vialla (FPV, Wright Medical UK) device was the second most commonly used patellofemoral unicompartmental prosthesis in the 2012 British National Joint Register. There are however no published outcomes data for this device. In this study, a total of 52 consecutive cases were studied prospectively using Oxford Knee Score and American Knee Society Scores pre-operatively and at follow-up to a minimum of 2 years. Overall Oxford Knee Scores improved from 30 points pre-operatively (36.6 %) to 19 points (60 %) at 1-year. American Knee Society Knee scores improved from 51 points pre-operatively to 81 points at 1-year. Function scores improved from 42 points pre-operatively to 70 points at 1-year. Moreover, 13 (25 %) patients had an excellent outcome with pain abolished and near normal knee function; 11 (21 %) patients gained very little improvement and scored their knees similar or worse to their pre-operative state. There were no infective or thromboembolic complications. Seven cases have been revised to a total knee replacement for on-going pain in 6 cases and progression of arthritis in the tibio-femoral compartments in 1 case. The patellar button was found to be very poorly fixed in all cases that were revised. The authors concluded that early results with the FPV prosthesis demonstrated that successful outcomes can be achieved; however the results were unpredictable and a significant minority of patients had on-going symptoms that they found unacceptable. They stated that the early revision rate was high in this series.
Al-Hadithy et al (2014) stated that isolated patellofemoral joint OA affects approximately 10% of patients aged over 40 years and treatment remains controversial. The FPV patellofemoral joint replacement has been shown to restore functional kinematics of the knee close to normal. Despite its increasing popularity in recent years, there are no studies evaluating the mid-term results with an objective scoring assessment. These investigators reported the clinical and radiological outcomes of FPV patellofemoral joint replacement in patients with isolated patellofemoral arthritis. Between 2006 and 2012, these researchers performed 53 consecutive FPV patellofemoral arthroplasties in 41 patients with isolated patellofemoral joint osteoarthritis. The mean follow-up was 3 years. Mean Oxford Knee Scores improved from 19.7 to 37.7 at latest follow-up. The progression of tibiofemoral osteoarthritis was seen 12% of knees. Two knees required revision to TKR at 7 months post-operatively, which these researchers attributed to poor patient selection. There were no cases of mal-tracking patellae, and no lateral releases were performed. The authors concluded that these findings suggested the FPV patellofemoral prosthesis provided good pain relief and survivorship with no significant mal-tracking patellae. This was a relatively small study (n = 41 patients) with mid-term results. These findings need to be validated by well-designed studies with larger sample size and long-term follow-up.

King et al (2015) reported the incidence of patellar fracture after PFA and determined associated factors as well as outcomes of patients with and without this complication. A total of 77 knees in 59 patients with minimum 2-year follow-up were included; 7 (9.1%) patients experienced a patellar fracture at a mean of 34 (range of 16 to 64) months post-operatively. All were treated non-operatively. Lower BMI (p = 0.03), change in patellar thickness (p < 0.001), amount of bone resected (p = 0.001), and larger trochlear component size (p = 0.01) were associated with a greater incidence of fracture. Fewer fractures occurred when the post-operative patellar height exceeded the pre-operatively measured height. No statistically significant differences were found in outcome scores between groups at mean four-year follow-up. A fair amount of fractures at mid-term; not sure if the incidence would increase at long-term.

Parratte et al (2015) noted that partial knee arthroplasty (PKA), either medial or lateral UKA or PFA are a good option in suitable patients and have the advantages of reduced operative trauma, preservation of both cruciate ligaments and bone stock, and restoration of normal kinematics within the knee joint. However, questions remain concerning long-term survival. These researchers presented the
long-term results of medial and lateral UKA, PFA and combined compartmental arthroplasty for multi-compartmental disease. Medium- and long-term studies suggested reasonable outcomes at 10 years with survival greater than 95 % in UKA performed for medial OA or osteonecrosis, and similarly for lateral UKA, particularly when fixed-bearing implants were used. Disappointing long-term outcomes have been observed with the 1st generation of patella-femoral implants, as well as early Bi-Uni (i.e., combined medial and lateral UKA) or bicompartamental (combined UKA and PFA) implants due to design and fixation issues. The authors concluded that promising short- and med-term results with the newer generations of PFAs and bicompartamental arthroplasties will require long-term confirmation.

Dudhniwala et al (2016) evaluated the early functional outcome and survivorship of a bicompartamental knee arthroplasty implant (Journey-Deuce) in a cohort of patients with combined medial and patella-femoral degenerative OA. A total of 15 patients with a mean age of 57 years were followed-up prospectively and evaluated with clinical examination, Oxford knee score and radiology imaging. Poor pain scores, concerns about the tibial fixation, early aseptic loosening of the tibial component and a revision rate of 60 % at a minimum follow-up of 54 months were reported. Implantation of this prosthesis was stopped at the authors’ institution well before the first revision due to an unfavorable early clinical response. This was further endorsed by an unacceptable revision rate. The authors concluded that the outcome of the Journey-Deuce bicompartamental knee replacement was considerably worse than the published outcome of TKR.

Sabatini et al (2016) stated that TKA is the most worldwide practiced surgery for knee OA and its effectiveness is mightily described by literature. Concerns about the invasiveness of TKA led the introduction of segmental resurfacing of the joint for younger patients with localized OA. Bone stock sparing and ligaments preservation are the essence of both UKA and BKA. Advantages related to BKA are the respect of knee biomechanics, lower complications rates, shorter hospital stay, faster rehabilitation. Moreover, in case of failure of the 1st implant the conversion to TKA is undemanding and can be compared to a standard prosthesis. The authors concluded that their experience suggested that BKA is a reliable technique in selected cases and especially younger people with higher functional requests can favorably profit from it. They stated that although these results are encouraging, there is still a need for further prospective, randomized, long-term studies to evaluate BKA indications and outcomes.
Staged Bicompartmental Knee Arthroplasty

Pandit and colleagues (2017) noted that lateral progression of arthritis following medial UKA, although infrequent, is still the most common reason for revision surgery. Treatment options normally include conversion to TKA. An alternative strategy for some patients may be addition of a lateral UKA. In an observational study, these investigators reported the first results of staged bi-compartmental UKA (Bi-UKA) strategy. They retrospectively selected from their UKA database patients who underwent a lateral UKA to treat a symptomatic lateral OA progression after a medial UKA. The analysis included a clinical and radiological assessment of each patient. A total of 25 patients for a total of 27 knees of staged Bi-UKA were performed in a single-center. The mean time interval between primary medial UKA and the subsequent lateral UKA was 8.1 years (SD ± 4.6 years). The mean age at the time of the Bi-UKA was 77.1 years (SD ± 6.5 years). The median hospital stay was 3 (range of 2 to 9 days) days, and the mean follow-up after Bi-UKA was 4 years (SD ± 1.9 years). The functional scores showed a significant improvement as compared to the pre-operative status (paired-t test, p = 0.003). There were no radiological evidences of failure. None of the patients needed blood transfusion, and there was no significant complications related to the surgical procedure without further surgeries or revisions at final follow-up. The authors concluded that these findings suggested that addition of a lateral UKA for arthritis progression following medial UKA is a good option in appropriately selected patients. Level of Evidence = IV. The main drawbacks of this study were its small sample size (n = 25), observational design (thus the lack of a control group), and medium term follow-up (mean of 4 years).

Customized Total Knee Implant

Beal et al (2016) stated that modern total knee arthroplasty (TKA) is effective at treating the pain and disability associated with osteoarthritis. The number of total knee replacements done in the USA continues to increase. Despite the great care taken during all of these procedures, some patients remain dissatisfied with their outcome. While this dissatisfaction is likely multi-factorial, malalignment of the prosthetic components is a major cause of post-operative complications. A neutral mechanical axis plus or minus 3° is felt to have a positive impact on the survivorship of the prosthesis. Conventional instrumentation has been shown to have a significant number of total knee replacements (TKRs) that lie well outside a neutral coronal alignment. With that in mind, significant effort has been placed into
the development of technology to improve the overall alignment of the prosthesis. In order to reduce the number of outliers, several companies have developed cost-effective systems to aid the surgeon in achieving a more predictably aligned prosthesis in all 3 planes. These researchers reviewed the literature that is available regarding several of these tools to examine if navigation or custom guides improve outcomes in TKA. The authors stated that the review supported that while both navigation and custom implants guides appeared to be a cost-effective way to achieve a predictable mechanical alignment of a total knee prosthesis therefore reducing the number of outliers, the cost may be increased operative times with no perceived difference in patient satisfaction with navigation custom guides. They concluded that while navigation and customized implants have found recent interest in the knee arthroplasty marketplace, in a broad sense and in their current forms, these technologies have yet to reach their full potential in improving outcomes and patient experience.

Huijbregts et al (2016) noted that patient-specific instrumentation (PSI) for TKA has been introduced to improve alignment and reduce outliers, increase efficiency, and reduce operation time. In order to improve the understanding of the outcomes of PSI, these researchers conducted a meta-analysis. They identified randomized and quasi-randomized controlled trials (RCTs) comparing patient-specific and conventional instrumentation in TKA. Weighted mean differences (WMDs) and risk ratios (RRs) were determined for radiographic accuracy, operation time, hospital stay, blood loss, number of surgical trays required, and patient-reported outcome measures. A total of 21 RCTs involving 1,587 TKAs were included. Patient-specific instrumentation resulted in slightly more accurate hip-knee-ankle axis (0.3°), coronal femoral alignment (0.3°, femoral flexion (0.9°), tibial slope (0.7°), and femoral component rotation (0.5°). The RR of a coronal plane outlier (greater than 3° deviation of chosen target) for the tibial component was statistically significantly increased in the PSI group (RR =1.64). No significance was found for other radiographic measures. Operation time, blood loss, and transfusion rate were similar. Hospital stay was significantly shortened, by approximately 8 hours, and the number of surgical trays used decreased by 4 in the PSI group. Knee Society scores and Oxford knee scores were similar. The authors concluded that PSI did not result in clinically meaningful improvement in alignment, fewer outliers, or better early patient-reported outcome measures. Efficiency is improved by reducing the number of trays used, but PSI did not reduce operation time.
Culler et al (2017) compared selected hospital outcomes between patients undergoing TKA using either a customized individually made (CIM) implant or a standard off-the-shelf (OTS) implant. A retrospective review was conducted on 248 consecutive TKA patients treated in a single institution, by the same surgeon. Patients received either CIM (n = 126) or OTS (n = 122) implants. Study data were collected from patients' medical record or the hospital's administrative billing record. Standard statistical methods tested for differences in selected outcome measures between the 2 study arms. Compared with the OTS implant study arm, the CIM implant study arm showed significantly lower transfusion rates (2.4 % versus 11.6 %; p = 0.005); a lower adverse event (AEs) rate at both discharge (CIM 3.3 % versus OTS 14.1 %; p = 0.003) and 90 days after discharge (CIM 8.1 % versus OTS 18.2 %; p = 0.023); and a smaller percentage of patients were discharged to a rehabilitation or other acute care facility (4.8 % versus 16.4 %; p = 0.003). Total average real hospital cost for the TKA hospitalization between the 2 groups were nearly identical (CIM $16,192 versus OTS $16,240; p = 0.913).

Finally, the risk-adjusted per patient total cost of care showed a net savings of $913.87 (p = 0.240) per patient for the CIM-TKA group, for bundle of care including the pre-operative computed tomography scan, TKA hospitalization, and discharge disposition. The authors concluded that patients treated with a CIM implant had significantly lower transfusion rates and lower AEs rates than patients treated with OTS implants. Patients treated with a CIM implant showed a trend toward a shorter LOS and a better discharge disposition than patients in the OTS arm. These improved outcomes for the CIM group were achieved without an increase in hospital costs. They stated that future studies are needed to examine the potential hospital savings associated with lower inventory management and sterilization cost-savings with the single package CIM implant.

The authors stated that there were several limitations to this analysis that warrant discussion. First, this analysis used a retrospective study at a single institution with a single surgeon. Care should be taken when extrapolating clinical outcome to other providers. However, it should be pointed out that the bias of the retrospective study was diminished due to the consecutive nature of patient enrollment and consistent patient management between both study arms. In addition, some of the clinical outcomes in the CIM study arm may reflect a learning curve associated with using a new implant device and outcomes, in particular, operation time may reflect the surgeons learning to use the device. A further limitation was that the study population (248 hospitalizations) limited the ability to reach statistical significance for some outcome measures. Nevertheless, nearly all the observed trends in
outcomes would have reached significance with more study patients and the same observed variance in the study. A third limitation was that hospital costs were estimated from billed charges. However, this was a well-established approach to estimate costs, and it was unlikely that the approach used to estimate cost would consistently over-estimate or under-estimate the cost of treating patients in either study group. Finally, increased focus on discharge planning over the study period may explain some of the observed differences in the proportion of patients discharged to home or home health care in the CIM study arm. However, this limitation was migrated by the fact that all patients were treated and discharged by the same surgeon.

Li et al (2017) noted that TKR has been performed for patients with end-stage knee joint arthritis to relieve pain and gain functions. Most knee replacement patients can gain satisfactory knee functions; however, the range of motion of the implanted knee is variable. There are many designs of TKR implants; it has been suggested by some researchers that customized implants could offer a better option for patients. Currently, the 3D knee model of a patient can be created from magnetic resonance imaging (MRI) or computed tomography (CT) data using image processing techniques. The knee models can be used for PSI design, biomechanical analysis, and creating bone cutting guide blocks. Researchers have developed patient-specific musculoskeletal lower limb model with TKR, and the models can be used to predict muscle forces, joint forces on knee condyles, and wear of tibial polyethylene insert. These available techniques make it feasible to create customized implants for individual patients. The authors concluded that customized TKR implant has the potential to greatly improve knee kinematics and patient knee functions compared to off-the-shelf TKR implant; however, further studies are need to be carried out to make the customized TKR implant available for patients.

Wang et al (2018) stated that newer TKR designs have been introduced to the market with the aim of overcoming common sizing problems with older TKR designs. Furthermore, since a sizable percentage of patients with osteoarthritis (OA) present with disease limited to the medial/lateral knee compartment in addition to the patellofemoral joint, for whom, a customized bi-compartmental knee replacement (BKR) is available as a therapeutic option. To-date, there is very little information regarding knee strength and mechanics during gait for patients implanted with these modern TKR and BKR designs. These investigators evaluated knee strength and mechanics during walking for patients with either a
modern off-the-shelf TKR or a customized BKR and compared these findings to a cohort of healthy controls. A total of 12 healthy controls, 8 BKR, and 9 TKR patients participated in the study. Maximal isometric knee strength was evaluated; 3D kinematic and kinetic analyses were conducted for level walking. The TKR knee exhibited less peak extensor torque when compared to, both the BKR and control limbs (p < 0.05). The TKR knee had less extensor moment at stance than both the BKR and control knees (p < 0.05). Both the BKR and control knees displayed larger internal rotation at stance than that of the TKR knee (p < 0.05).

The authors concluded that the findings of this study suggested that, for patients that exhibit isolated OA of the tibiofemoral joint, using a customized BKR implant is a viable therapeutic option and may contribute to superior mechanical advantages.

The authors stated that there were several drawbacks that need consideration when interpreting these results. The sample size of participants in each group was smaller than the typical follow-up studies that reported on functional and clinical end-points. Though sample size played an important role in interpreting results, the authors believed from their experience with conducting such studies, that the sample size chosen was adequate to enable them to make conclusions on their analyses. Additionally, they were able to maintain a similar sample size in each arm of the study. This should alleviate any bias due to sample size in any one study arm. Although participants in the control group were younger with smaller BMI than the other groups, the 2 patient groups were age-, mass-, and height-matched. These investigators believed that any advantage drawn from this would affect the implant groups equally, thus making comparisons between the implant groups relevant, while still providing context on how they compare to healthy controls. Ideally, the authors would have liked to test patients pre- and post-operatively and compare results with the patient being their own control. However, this would mean having to test patients that have end-stage OA, which the authors felt would not provide a clear comparison to healthy controls. Lastly, in this study, patients’ pre-operative Knee Society scores and gait analysis data were not available due to their cross-sectional study design. However, they believed their patients’ pre-surgical conditions were similar to patients used in other prospective studies examining functional improvements after knee replacements. In those studies, patients’ combined Knee Society scores were close to 100 and knee range of motion was around 120° [19, 20, 21, 22]. In general, patients with end-stage knee OA experience joint pain and stiffness, which led to functional limitations of performing daily activities such as walking, going up and down stairs, and rising from a sitting position. The authors chose the KOS-ADL because it is an effective
instrument for measuring functional limitations associated with pathological disorders of the knee. However, the authors only administered the KOS-ADL during patients’ post-operative laboratory visit. Ideally, if the KOS-ADL score was obtained prior to surgery, then it would have been possible to quantify how much functional improvement was made at the time of the post-operative laboratory testing.

Prophylactic Radiation Therapy Following Total Knee Arthroplasty

Chidel and colleagues (2001) stated that heterotopic ossification (HO) occurs in 42% of patients who have undergone total knee arthroplasty (TKA). Bone formation usually is found in the quadriceps expansion and causes minimal to no symptoms. Specific therapy usually is unnecessary, but cases have been reported in which manipulation under anesthesia (MUA) or revision arthroplasty has been required. These investigators reported a small series of 5 patients (6 knees) who have undergone surgical intervention for HO of the knee with radiotherapy given post-operatively for prophylaxis against future HO. The authors concluded that although this series was small, it appeared that the use of prophylactic radiation may reduce recurrence after resection of symptomatic HO after TKA. Moreover, they stated that further investigation is needed to confirm these preliminary findings.

Farid and associates (2013) noted that therapeutic options for arthrofibrosis following TKA include MUA, open or arthroscopic arthrolysis, and revision surgery to correct identifiable problems. These investigators proposed pre-operative low-dose irradiation and Constrained Condylar or Rotating-hinge revision for severe, idiopathic arthrofibrosis. Irradiation may decrease fibro-osseous proliferation while constrained implants allow femoral shortening and release of contracted collateral ligaments. A total of 14 patients underwent 15 procedures for a mean overall motion of 46° and flexion contracture of 30°; 1 patient had worsening range of motion (ROM) while 13 patients had 57° mean gain in ROM (range of 5° to 90°). Flexion contractures decreased by a mean of 28°. There were no significant complications at a mean follow-up of 34 months (range of 24 to 74 months).

Furthermore, an UpToDate review on “Total knee arthroplasty” (Martin and Crowley, 2018) does not mention radiation therapy/radiotherapy for post-operative management.
CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>+0396T</td>
<td>Intra-operative use of kinetic balance sensor for implant stability during knee replacement arthroplasty (List separately in addition to code for primary procedure)</td>
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<tr>
<td>77401</td>
<td>Radiation treatment delivery [following total knee arthroplasty]</td>
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Other CPT codes related to the CPB:

<table>
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<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>27437</td>
<td>Arthroplasty, patella; without prosthesis</td>
</tr>
<tr>
<td>27438</td>
<td>with prosthesis</td>
</tr>
<tr>
<td>27440</td>
<td>Arthroplasty, knee, tibial plateau</td>
</tr>
<tr>
<td>27441</td>
<td>with debridement and partial synovectomy</td>
</tr>
<tr>
<td>27442</td>
<td>Arthroplasty, femoral condyles or tibial plateau(s), knee</td>
</tr>
<tr>
<td>27443</td>
<td>with debridement and partial synovectomy</td>
</tr>
<tr>
<td>27445</td>
<td>Arthroplasty, knee, hinge prosthesis (eg, Walldius type)</td>
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Total knee arthroplasty (TKA):

CPT codes covered if selection criteria are met:

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<th>Code Description</th>
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<tr>
<td>27447</td>
<td>Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)</td>
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HCPCS codes covered if selection criteria are met:

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<th>Code Description</th>
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<tr>
<td>C1776</td>
<td>Joint device (implantable) [FDA approved device]</td>
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ICD-10 codes covered if selection criteria are met:

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<td>Osteoarthritis of knee [with radiographic evidence]</td>
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<td>M17.9</td>
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ICD-10 codes not covered if selection criteria are met:

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<th>Code Description</th>
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<td>A00.0</td>
<td>Infectious and parasitic diseases</td>
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<td>B99.9</td>
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<td>G61.0</td>
<td>Guillain-Barre syndrome</td>
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<td>L08.0</td>
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<td>L08.81</td>
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<tr>
<td>L88</td>
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<td>M00.861</td>
<td>Arthritis due to other bacteria, knee</td>
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<tr>
<td>M00.869</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
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<tr>
<td>M01.X61 - M01.X69</td>
<td>Direct infection of knee in infectious and parasitic diseases classified elsewider</td>
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<tr>
<td>S81.001+ - S81.859</td>
<td>Open wound of knee and lower leg</td>
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<tr>
<td>T78.40x+</td>
<td>Allergy, unspecified, NEC [allergy to components of the implant]</td>
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Revision or replacement of total knee arthroplasty:
CPT codes covered if selection criteria are met:

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<th>Code Description</th>
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<td>Revision of total knee arthroplasty, with or without allograft</td>
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<tr>
<td>27488</td>
<td>Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee</td>
</tr>
</tbody>
</table>

HCPCS codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1776</td>
<td>Joint device (implantable) [not covered for customized total knee implant]</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M89.9</td>
<td>Disorder of bone, unspecified [confirmed by imaging]</td>
</tr>
<tr>
<td>M94.9</td>
<td>Disorder of cartilage, unspecified [confirmed by imaging]</td>
</tr>
<tr>
<td>M97.11x+ - M97.12x+</td>
<td>Periprosthetic fracture around internal prosthetic, knee joint [confirmed by imaging]</td>
</tr>
<tr>
<td>T84.012+ - T84.013+</td>
<td>Broken internal knee prosthesis [confirmed by imaging]</td>
</tr>
<tr>
<td>T84.022+ - T84.023+</td>
<td>Instability of internal knee prosthesis</td>
</tr>
<tr>
<td>T84.032+ - T84.033+</td>
<td>Mechanical loosening of prosthetic joint [confirmed by imaging]</td>
</tr>
<tr>
<td>T84.062+ - T84.063+</td>
<td>Wear of articular bearing surface of internal prosthetic knee joint [confirmed by imaging]</td>
</tr>
<tr>
<td>T84.092+ - T84.093+</td>
<td>Other mechanical complication of internal knee prosthesis [confirmed by imaging]</td>
</tr>
<tr>
<td>Z96.651 - Z96.659</td>
<td>Presence of artificial knee joint</td>
</tr>
</tbody>
</table>

Unicompartmental knee arthroplasty:
CPT codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>27446</td>
<td>Arthroplasty, knee, condyle and plateau; medial OR lateral compartment</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>------</td>
<td>-----------------</td>
</tr>
<tr>
<td><strong>HCPCS codes covered if selection criteria are met:</strong></td>
<td></td>
</tr>
<tr>
<td>C1776</td>
<td>Joint device (implantable) [not covered for customized total knee implant]</td>
</tr>
<tr>
<td><strong>ICD-10 codes covered if selection criteria are met:</strong></td>
<td></td>
</tr>
<tr>
<td>M17.0 - M17.9</td>
<td>Osteoarthritis of knee [with radiographic evidence]</td>
</tr>
<tr>
<td>UniSpacer interpositional spacer:</td>
<td></td>
</tr>
<tr>
<td><strong>No specific code</strong></td>
<td></td>
</tr>
<tr>
<td><strong>ICD-10 codes not covered if selection criteria are met (not all inclusive):</strong></td>
<td></td>
</tr>
<tr>
<td>M17.0 - M17.9</td>
<td>Osteoarthritis of knee</td>
</tr>
<tr>
<td>Bicompartamental, bi-unicompartmental knee and staged bicompartamental arthroplasty:</td>
<td></td>
</tr>
<tr>
<td><strong>No specific code</strong></td>
<td></td>
</tr>
<tr>
<td><strong>ICD-10 codes not covered if selection criteria are met (not all inclusive):</strong></td>
<td></td>
</tr>
<tr>
<td>M17.0 - M17.9</td>
<td>Osteoarthritis of knee</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


75. Martin GM, Crowley M. Total knee arthroplasty. UpToDate Inc., Waltham, MA. Last reviewed April 2018.
AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0660
Unicompartmental, Bicompartmental, and Bi-unicompartmental Knee Arthroplasties

There are no amendments for Medicaid.