Clinical Policy Bulletin:  
Unicompartmental, Bicompartmental, and Bi-unicompartmental Knee Arthroplasties

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Policy

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 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. Weight reduction as appropriate; and
6. Assistive device use (required for persons with relative contraindications* to joint replacement, optional for others), and
7. 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 six (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 posttraumatic 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. Weight reduction as appropriate; and
6. Assistive device use (required for persons with relative contraindications* to joint replacement, optional for others), and
7. 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 bicompartamental and bi-unicompartmental knee arthroplasty experimental and investigational for osteoarthritis of the knee and all other indications because their 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 17), these researchers do not recommend this system despite the expected improvements on this range of implants.

It has been suggested that bicompartamental knee replacement may be indicated for individuals with osteoarthritis limited to the medial and patello-femoral compartments. Bicompartamental 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 bicompartamental 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 bicompartamental 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 bicompartamental 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 bicompartamental 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 bicompartamental 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 bicompartamental 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 bicompartmental tibio-femoral knee arthritis with an asymptomatic patello-femoral joint. A total of 22 patients with bicompartamental 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 a 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 bicompartmental 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 bicompartamental 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 bicompartmental arthroplasty is an emerging knee-resurfacing approach that provides a conservative alternative to TKA. Isolated bicompartmental 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 bicompartmental 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 bicompartmental 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 bicompartamental implants but longer-term durability has not been documented. These investigators examined if (i) bicompartamental arthroplasty (either combined medial unicompartmental UKA and femoro-patellar arthroplasty (PFA) or medial UKA/PFA, or combined medial and lateral UKA or bicompartamental UKA) reliably improved Knee Society pain and function scores; (ii) bicompartamental 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 bicompartamental 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
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 bicompartmental 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 bicompartmental 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 bicompartmental arthroplasty. A literature review of all peer-reviewed published articles on bicompartmental arthroplasty of the knee was performed. Bicompartmental 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. Bicompartmental 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 bicompartmental arthroplasty is an excellent alternative to treat bicompartmental 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 bicompartmental 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
The results of medial and lateral UKA, PFA and combined compartmental arthroplasty for multicompartamental 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 bicompartmental (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 bicompartmental arthroplasties will require long-term confirmation.

Dudhniwala et al (2016) evaluated the early functional outcome and survivorship of a bicompartmental 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 bicompartmental 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 let 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.

### 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 "+":

#### CPT codes not covered for indications listed in the CPB:

+0396T Intra-operative use of kinetic balance sensor for implant stability during knee replacement arthroplasty (List separately in addition to code for primary procedure)

#### Other CPT codes related to the CPB:

- 27437 Arthroplasty, patella; without prosthesis
- 27438 with prosthesis
- 27440 Arthroplasty, knee, tibial plateau
- 27441 with debridement and partial synovectomy
- 27442 Arthroplasty, femoral condyles or tibial plateau(s), knee
with debridement and partial synovectomy

**Total knee arthroplasty (TKA):**

**CPT codes covered if selection criteria are met:**

- 27447  Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)

**HCPCS codes covered if selection criteria are met:**

- C1776  Joint device (implantable) [FDA approved device]

**ICD-10 codes covered if selection criteria are met:**

- M17.0 - M17.9  Osteoarthritis of knee [with radiographic evidence]

**ICD-10 codes not covered if selection criteria are met:**

- A00.0 - B99.9  Infectious and parasitic diseases
- G61.0  Guillain-Barre syndrome
- L08.0, L08.81, L88  Pyoderma
- M00.861 - M00.869  Arthritis due to other bacteria, knee
- M01.X61 - M01.X69  Direct infection of knee in infectious and parasitic diseases classified elsewhere
- S81.001+ - S81.859  Open wound of knee and lower leg
- T78.40x+  Allergy, unspecified, NEC [allergy to components of the implant]

**Revision or replacement of total knee arthroplasty:**

**CPT codes covered if selection criteria are met:**

- 27486 - 27487  Revision of total knee arthroplasty, with or without allograft
- 27488  Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee

**HCPCS codes covered if selection criteria are met:**

- C1776  Joint device (implantable) [FDA approved device]

**ICD-10 codes covered if selection criteria are met:**

- M89.9  Disorder of bone, unspecified [confirmed by imaging]
- M94.9  Disorder of cartilage, unspecified [confirmed by imaging]
- M97.11x+ - M97.12x+  Periprosthetic fracture around internal prosthetic, knee joint [confirmed by imaging]
Broken internal knee prosthesis [confirmed by imaging]

Instability of internal knee prosthesis

Mechanical loosening of prosthetic joint [confirmed by imaging]

Wear of articular bearing surface of internal prosthetic knee joint [confirmed by imaging]

Other mechanical complication of internal knee prosthesis [confirmed by imaging]

Presence of artificial knee joint

**Unicompartmental knee arthroplasty:**

**CPT codes covered if selection criteria are met:**

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**UniSpacer interpositional spacer:**

No specific code

**ICD-10 codes not covered if selection criteria are met (not all inclusive):**

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<td>Osteoarthritis of knee</td>
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**Bicompartmental and bi-unicompartmental knee arthroplasty:**

No specific code

**ICD-10 codes not covered if selection criteria are met (not all inclusive):**

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<tr>
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<td>Osteoarthritis of knee</td>
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The above policy is based on the following references:


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.

www.aetnabetterhealth.com/pennsylvania  new 9/1/2017