



CIGNA MEDICAL COVERAGE POLICY

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Subject **Knee Arthroplasty/Replacement**

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Computer-Assisted Surgical Navigation for Musculoskeletal Procedures, Including Spinal
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Coverage Policy

CIGNA covers a total knee replacement as medically necessary when there is radiographic evidence of advanced knee joint disease, due to conditions such as osteoarthritis, rheumatoid arthritis, osteonecrosis, or traumatic arthritis, when ALL of the following criteria are met:

- radiological evidence of articular cartilage loss and severe joint destruction with findings of bone-on-bone changes (e.g., Outerbridge Grade IV, Kellgren-Lawrence Grade 4)
- persistent knee pain despite an appropriate course of nonsurgical management (e.g., nonsteroidal anti-inflammatory agents [NSAIDs], analgesics, light exercise, assistive device, bracing, viscoelastic supplementation)
- functional limitation resulting in impaired, age-appropriate activities of daily living, secondary to the knee resulting in a diminished quality of life

CIGNA covers a revision of total knee replacement as medically necessary when ANY of the following conditions are met:

- recurrent disabling knee pain, stiffness and functional limitation that has not responded to appropriate nonsurgical management
- fracture or dislocation of the patella
- instability of the components or aseptic loosening
- deep infection, with or without symptoms of systemic toxicity
- periprosthetic fractures

CIGNA covers a unicompartmental knee replacement (i.e., partial replacement, single compartment) as medically necessary as an alternative to total knee replacement for advanced knee joint disease due to conditions such as osteoarthritis, osteonecrosis, and traumatic arthritis, when ALL of the following conditions are met:

- radiological evidence of articular cartilage loss and severe joint destruction with findings of bone-on-bone changes (e.g., Outerbridge Grade IV, Kellgren-Lawrence Grade 4) limited to a single compartment
- knee examinations demonstrate good alignment and ligamentous stability
- persistent knee pain despite an appropriate course of nonsurgical management (e.g., NSAIDs, analgesics, light exercise, assistive device, bracing, viscoelastic supplementation)
- functional limitation resulting in impaired, age-appropriate activities of daily living, secondary to the knee resulting in a diminished quality of life

CIGNA does not cover ANY of the following because each is considered experimental, investigational or unproven:

- bicompartamental knee replacement, including bi-unicompartmental
- computer assisted guidance during knee arthroplasty
- customized knee replacement prostheses, including gender specific
- minimally invasive approaches to knee arthroplasty
- unicondylar interpositional spacer (e.g., UniSpacer[®])

General Background

The knee joint functions as a complex hinge system to allow flexion and extension movement, in addition to rotation and gliding movement. The knee joint is made up of three compartments: the lateral, medial and patellofemoral. Medical conditions such as osteoarthritis, ligament instability and trauma result in symptoms such as knee pain, stiffness of joints, locking of the joint or giving way of the joint. Nonoperative treatment often consists of activity modification, exercise programs, weight loss, knee braces, orthotics, anti-inflammatory medications and injections. Surgical treatment options include knee arthroscopy, osteotomy, partial knee replacement, and total knee replacement (TKR).

Total knee replacement is one of the most common orthopedic procedures performed and is also referred to as knee arthroplasty. The terms "joint arthroplasty" and "joint replacement" are often used interchangeably in the medical literature. Joint arthroplasty refers to reshaping, reconstructing or replacing a diseased or damaged joint while joint replacement refers to the surgical replacement of a joint with an artificial prosthesis.

Emerging technologies aimed at improving clinical outcomes associated with TKR include minimally invasive surgical approaches, computer-aided navigation and computer-aided robotic-assisted procedures. Other technologies such as custom made knee replacement prostheses (e.g., Custom Fit Knee™ Replacement [OtisMed Corp., Alameda, CA]) which may include patient specific instrumentation, and gender-specific total knee prostheses (e.g., Gender Solutions™ High Flex Knee [Zimmer Inc., Warsaw, IN]) are being investigated. However, there is a paucity of data evaluating these technologies and improved health outcomes in comparison to standard well-established approaches have yet to be demonstrated.

Knee joint failure often results from advanced joint disease (i.e., end stage disease) which generally involves complete destruction of cartilage (i.e., bone-on-bone changes). Several grading systems are available to grade articular cartilage disease. The Outerbridge classification is the most widely used system of judging articular injury to the knee. This system allows delineation of varying areas of chondral pathology based on the qualitative appearance of the cartilage surface, and can assist in identifying those injuries that are suitable for repair techniques. The characterization of cartilage in this system is:

- Grade 0: normal
- Grade I: cartilage with softening and swelling

- Grade II: a partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter
- Grade III: fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm
- Grade IV: subchondral bone exposed

A second system often used for grading cartilage disease is the Kellgren-Lawrence grading scale. According to this scale injury is defined as follows:

- Grade 1: doubtful narrowing of joint space and possible osteophytic lipping
- Grade 2: definite osteophytes, definite narrowing of joint space
- Grade 3: moderate multiple osteophytes, definite narrowing of joints space, some sclerosis and possible deformity of bone contour
- Grade 4: large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour

The two scales are comparable with the end point of Grade IV/4 being what is usually described as bone-on-bone. As the grade of disease increases, there is a stronger association with symptoms such as pain, stiffness and swelling.

Total Knee Replacement (TKR)

During TKR a thin layer of subchondral bone and overlying articular cartilage is removed, in addition to anatomic resurfacing of all three compartments with insertion of a metal implant and polyethylene bearing surface. The implants are either fixed with bone cement or are cementless.

Primary TKR is most commonly performed for knee joint failure caused by osteoarthritis (OA) with the goal of relieving pain and improving function (National Institutes of Health [NIH], 2003). In addition to osteoarthritis, advanced joint disease with destruction of cartilage often results from conditions such as inflammatory arthritis, rheumatoid arthritis, post-traumatic arthritis/deformity, and osteonecrosis.

Clinical outcomes reported in the published literature support decreased pain and improved function and mobility (Kane, et al., 2003; Satku, 2003; NIH, 2003). Long-term survivorship of the implant has been reported as 94-98% at 15 years post surgery (Meek, et al., 2004).

U.S. Food and Drug Administration (FDA): Artificial joints, such as the knee joint prosthesis, are regulated by the FDA as Class II devices.

Revision of Total Knee Replacement: Knee prostheses are generally very durable and good to excellent clinical outcomes have been reported in the medical literature. Prosthesis survivorship, free from revision, has been reported to exceed 90% at long-term follow-up. However, in some cases failure does occur, requiring a revision of the TKR.

Conditions that contribute to the need for revision of TKR include disabling pain, stiffness, and functional limitations unrelieved by appropriate nonsurgical management and lifestyle changes. Evidence of progressive and substantial bone loss alone is considered sufficient reason to consider revision in advance of catastrophic prosthesis failure; furthermore, fracture or dislocation of the patella, instability of the components or aseptic loosening, infection, and periprosthetic fractures are also common reasons for total knee revision (NIH, 2003).

Unicompartmental Knee Replacement (UKR)

Unicompartmental OA can occur in any of three existing compartments of the joint: medial, lateral, or patellofemoral. In comparison to TKR, UKR is typically recommended for individuals with less severe disease, and who have better knee function. During a unicompartmental knee replacement only a single compartment is replaced; only the bony area in the single damaged compartment needs to be resurfaced. The ends of the femur and tibia are capped with metal coverings and a plastic insert is placed between the two metal components for smooth gliding. Evidence suggests that with appropriate patient selection UKRs are a successful option for patients with OA of the knee. UKR may be performed through standard exposure or utilizing minimally invasive surgery with modified instruments.

Medial or Lateral Compartment: Unicompartmental knee replacement has been proposed as an alternative to TKR for patients with disease limited to the medial or lateral compartment, with the proposed advantages being less pain, quicker recovery and better long-term results. A unicompartmental knee replacement requires a smaller and less invasive incision that does not interrupt the anterior and posterior cruciate ligaments which are the main muscles controlling the knee (American Academy of Orthopaedic Surgeons [AAOS], 2006).

UKA is considered to be as safe and effective as TKA and high tibial osteotomy, although it is associated with a risk for development or progression of disease in adjacent compartments. Published scientific data confirm medium- to long-term outcomes associated with unicompartmental replacement are comparable to those of primary TKR in select patient groups (Dabov and Perez, 2003; Meek et al., 2004; Koopman and Moreland, 2005). Clinical studies have shown that patients treated with unicompartmental knee replacement have better functionality and greater range of motion than patients treated with total knee replacement (Rougraff, et al., 1991; Newman, et al., 1998). Authors have also reported on the survival rate of prostheses, most of which approach at least 10 years (Murray, et al., 1998; Berger, et al., 1999). Newman et al. (2009) reported the 15 year follow-up results of the study published in 1998, and noted a 15 year survivorship rate, based on revision or failure for any reason, was 89.8% for UKR compared to 78.7% for TKR. In addition, it is possible that in later years a patient could wear out the initial knee replacement, thus requiring a second procedure (i.e., revision). Research has shown that a unicompartmental knee implant can be revised more easily than a total knee replacement.

Patellofemoral Replacement: Isolated OA of the patellofemoral joint is not a common occurrence. Surgical treatment for isolated patellofemoral arthritis has been proposed for patients with disabling isolated arthritis or degeneration of the patellofemoral compartment, who have failed to respond to other conservative and/or surgical treatment options, and/or is unwilling to undergo other surgical alternatives such as patellectomy or TKR. Patellectomy has been associated with poor clinical outcomes and as a result is not often recommended. TKR, particularly in younger more active individuals, is often discouraged due to complexities of the procedure, need for future revision and residual pain (Leadbetter, et al., 2008). Results of other procedures for treating patellofemoral arthritis, such as chondroplasty, lateral release, soft tissue reconstruction, realignment osteotomy, and resurfacing procedures, can lead to lengthy recovery and variable outcomes. A patellofemoral knee replacement, similar to a unicompartmental replacement, replaces only the worn articular surface underneath the patella and its articulating trochlear surface. Potential advantages of patellofemoral replacement include a less invasive approach, less bone resection and tissue destruction, decreased operative time, and blood loss, shorter rehabilitation, and more normal knee kinematics.

Literature Review: Evidence evaluating newer implant designs suggests improved short- to mid-term survivorship rates and lends support to patellofemoral arthroplasty as an alternative to TKR (Odumenya, et al., 2010; van Jonbergen, et al., 2010;). Although evidence is limited, there is some recent data supporting long-term safety and efficacy (van Jonbergen, et al., 2010). Some of the published literature involves patient populations that overlap and many of the available studies are in the form of retrospective and prospective case series and lack randomized controlled trials (Meding, et al., 2007; Ackroyd, et al., 2007; Sisto and Sarin, 2006; Ackroyd and Chir, 2005; Leadbetter, et al., 2005). Follow-up across earlier published studies range from a mean duration of 3.75 years to 17 years (Argenson, et al., 2005; Merchant, 2004; Kooijman, et al., 2003; Smith, et al., 2002; Tauro, et al., 2001; de Winter et al., 2001). Various scales have been used to assess clinical outcomes, and include the ADL scale, Knee Society scores, follow-up radiographs, modified Hungerford and Kenna knee score, the Bristol Knee score, and subjective questionnaires, making comparisons across studies difficult. However, good and excellent results ranged from 45% to 93% across these specific studies.

Revision rates and survivorship also vary across studies. Delanois et al. (2008) conducted a review of the literature and reported that survival rates for patellofemoral arthroplasty ranged as follows: 95% to 100% at a mean follow-up of five years, 85% to 90% at seven to eight years, was 75% at 10 years and 58% at 16 years. Of the studies reviewed, more than 99% of failures were attributed to progression of OA in the tibiofemoral compartments; those knees were revised to TKR. In addition to the revisions, 6% to 44% of the patients experienced joint pain and had arthritic changes in the tibiofemoral compartments five to seven years following the patellofemoral arthroplasty. Revision is often performed as result of progression of OA, malposition, loosening, stiffness, maltracking and/or wear and tear of the patellar component (Anderson, et al, 2005; .Kooijman, et al., 2003; Smith, et al., 2002; de Winter, et al., 2001). Survivorship as reported by other authors has been 100% at 3.75 years (Merchant, 2004), 58% at six years (Argenson, et al., 2005) and 65% at eight years (Smith, et al., 2002). Argenson et al. (2005) (n=66) reported revision surgery was performed in 14 patients for tibiofemoral OA, in 11 for loosening, and in four for stiffness. Survivorship was 58% at six years. Merchant

(2004) (n=15) reported no implant failures at an average of 3.75 years follow-up. Kooijman et al. (2003) reported a 15.5% revision rate, and that 12 out of a study group of 45 patients required further surgery due to tibiofemoral OA, ten of which required a conversion to a TKR after a mean of 15.6 years. The mean survival time was $19.5 \pm .45$ years. With a mean follow-up of 49 months, Smith et al. (2002) (n=34) reported a 19% revision rate to either a TKR or a repeat patellofemoral replacement (due to maltracking). In this study, survivorship was not reported. Tauro et al. (2001) (n=48) reported a 28% revision surgery rate giving a cumulative survival rate of 65% at eight years. de Winter et al. (2001) reported that out of a group of 24 patients followed for an average of 11 years, three cases required revision surgery for patellectomy, and two required conversion to TKR for progressive tibiofemoral OA or patella malalignment (21% rate); (survivorship was not specifically reported by this group of authors). In general, the investigators suggested clinical results were dependent on prosthetic design, patient selection and technical proficiency.

The effect of patellofemoral arthroplasty on a future TKR has also been studied. In 2009 van Jonbergen and colleagues evaluated whether or not patellofemoral arthroplasty compromised the results of total knee arthroplasty. The authors compared 13 subjects who underwent patellofemoral arthroplasty and required TKR with a control group of 13 subjects who underwent primary TKR. The results of the study demonstrated patellofemoral arthroplasty did not have a negative effect on the outcome of later TKR (Jonbergen, et al., 2009). Lonner et al. (2006) also evaluated patients who received TKR after patellofemoral arthroplasty (n=12) to determine if results are compromised by prior arthroplasty. The mean interval to revision TKR for this study group was four years (range of one to 9.7). The results of this study suggested that TKR was not compromised when revision was performed for a failed patellofemoral replacement. Furthermore, the authors of this study noted the primary implants were able to be utilized again unless the patellar component was worn, loose or malpositioned.

Reported short-term and mid-term results for patellofemoral arthroplasty vary across studies but in general support improvement in pain, function and mobility (. The use of custom-designed patellofemoral prosthetic devices versus off-the-shelf designs and computer guidance have been utilized aimed at improving clinical outcomes, however published data evaluating these methods are lacking. Patellofemoral arthroplasty is associated with progression of OA in surrounding compartments and revision to TKR; however it is unclear as to which patients are specifically at risk for development of tibiofemoral OA. Patient selection criteria have not been clearly defined, although potential candidates include individuals with severe isolated patellofemoral OA who have failed other treatments, are not candidates for or have failed other surgical options, have residual pain, and/or are unwilling to undergo TKR. Although there is no general consensus, patellofemoral arthroplasty may be considered a salvage procedure prior to a TKR.

Bicompartmental Knee Replacement/Bi-unicompartmental Knee Replacement

Some evidence in the published literature suggests that bicompartmental knee replacement may be indicated for patients with disease limited to the medial and patellofemoral compartments. With one approach, the bicompartmental knee replacement, only the diseased medial and patellofemoral compartments are replaced while sparing the lateral compartment and cruciate ligaments. In theory, retention of the cruciate ligament(s) maintains more normal knee function and mobility. It has been suggested this approach is associated with less pain and reduced tissue trauma, resulting in a more rapid recovery (Rolston, et al., 2007). Bi-unicompartmental replacement has also been reported in the published literature. This approach has been used for treating bicompartmental (i.e., medial and lateral) arthritis (Confalonieri and Manzotti, 2006).

In 2010 Heyse et al. reported the results of a retrospective case series involving nine subjects who underwent medial and patellofemoral bicompartmental arthroplasty. The average follow-up was 11.8 ± 5.4 years and included radiologic evaluations and clinical scores (KSS and WOMAC). The authors noted there were no surgical revisions, the KSS and WOMAC scores were improved and all patients were satisfied or very satisfied with the outcomes. Although the results are encouraging, this study is limited by small sample population and the results cannot be generalized to larger populations (Heyse, et al., 2010).

Parratte et al. (2010) reported the results of a retrospective case series evaluating bicompartmental arthroplasty (n=155; 84 had bi-unicompartmental and 71 had medial UKA and patellofemoral). The minimum follow-up was five years, average 11.7, and ranged from 5-23 years using Knee Society, function scores and radiographs. Bicompartmental arthroplasty relieved pain and improved Knee Society and function scores. Results were mixed in regard to durability; a 17 year survival to revision, radiograph loosening or disease progression was 78% in the group of subjects who underwent bi-unicompartmental replacement and 54% in the group who

underwent medial unicompartamental/patellofemoral replacement. The authors reported 17 revisions in the bi-UKA group and 28 in the med-UKA/PFA group.

In 2008 Confalonieri et al. reported the results of a comparison of 22 patients who underwent bi-unicompartamental knee replacement with a similar group who underwent computer assisted TKR. The authors noted that at 48 months follow-up there were no statistical differences in surgical time, Knee Society scores, Functional and Italian Orthopaedic UKR Users Group score between groups. There was a statistically significant difference in WOMAC Function and Stiffness score in favor of the Bi-Uni group. TKR implants were statistically better aligned and positioned. As noted by the authors, these results suggest that Bi-UKR is a viable option; however, the study is flawed by its retrospective design, lack of randomization, use of different implants and different alignment systems (Confalonieri, et al., 2008).

In order to estimate the utility of the Journey Deuce™ Knee System (Smith and Nephew Inc., Memphis, TN), a bicompartamental prosthetic device, Rolston and colleagues (2007) reported the results of a series of 95 patients who were implanted with the bicompartamental device since 2003. Follow-up for this group of patients extended 33 months. The authors reported the following: 82 of 95 patients were discharged two days after surgery, the average range of motion for the group was 0° to 117°, most patients were able to walk without an assistive device two weeks post-surgery, and there was less blood loss compared to that for TKR patients. In addition, there was no lateral joint line tenderness and the patients did not have patellofemoral pain.

In 2006, Confalonieri and Manzotti reported the results of a retrospective analysis of bi-unicompartamental knee replacement performed on 24 knees with bicompartamental arthritis (medial and lateral). Clinical outcomes were evaluated at a minimum follow-up of 36 months and included Knee Society scores and a dedicated UKR score. The authors noted there were no revisions and all clinical scores were improved and were similar to TKR.

Callahan et al. (1995) reported the results of a meta-analysis evaluating unicompartamental and bicompartamental knee replacement. The authors reviewed 46 studies evaluating UKR involving 2391 patients and a mean follow-up of 4.6 years. For the bicompartamental evaluation, the total number of enrolled patients was 844, mean follow-up was 3.6 years, and there were a total of 18 studies. The authors reported that outcomes for the bicompartamental knee replacement appeared worse compared to the UKR, although they noted that patients who underwent the bicompartamental approach had poorer baseline knee function. Consequently, no reliable conclusions regarding efficacy could be made.

Supporting evidence in the published scientific literature is limited and does not allow strong conclusions regarding improved patient outcomes with either a bi-unicompartamental or bicompartamental approach. There is no consensus among authors for optimal patient selection criteria and the advantages of performing bicompartamental or bi-unicompartamental knee replacement in comparison to standard treatment options such as TKR, have not been clearly established in the scientific literature.

Minimally Invasive Techniques

Standard surgical approaches to knee replacement allow for greater visibility and safe mobilization of the tissues. Minimally invasive approaches have been investigated with the intention of limiting surgical dissection without compromising the surgical procedure or patient outcomes. Minimally invasive surgical (MIS) approaches involves two developments: a smaller incision and a new technology approach (Vail, 2004). The MIS TKR incision is 4–6 inches long (AAOS, 2005). The main difference between a traditional approach and the MIS approach is the method in which the surgeon exposes and gains access to the joint—a minimally invasive approach has a smaller incision and avoids patella eversion and quadriceps muscle splitting. Furthermore, a minimally invasive approach to the knee should not violate the extensor mechanism or the suprapatellar pouch (AAHKS, 2004; Haas, et al., 2004; Tria and Coon, 2003). Modifications of the medial parapatellar, subvastus and midvastus approaches applying MIS techniques have been published in the literature (Scuderi, et al., 2004), however, patient selection criteria have not been clearly established. Less invasive surgical implants (e.g., unicompartamental knee arthroplasty) use different components and incision methods and should be evaluated as a separate type of less invasive surgery.

Surgical techniques for minimally invasive approaches have been facilitated by the use of smaller instrumentation; nonetheless, choice of prosthetic type is limited. In addition, MIS methods involve the risk of inaccurate implant positioning and possible additional complications, due to a restricted operative field. Incorrect positioning or orientation of implants during TKR, poor soft tissue balancing, and improper alignment of the limb

can lead to accelerated wear, loosening and decreased overall performance of the implant (DiGioia, et al., 2004). Malalignment alone can lead to abnormal patellar tracking, increased polyethylene wear, early loosening, and poor functional outcome (Chin, et al., 2007). Methods of improving accurate positioning of knee replacement with computer-guided instruments (i.e., computer navigational systems) have been proposed by some authors, although potential benefits and associated risks have not been clearly established. Although it has not been updated, the Blue Cross Blue Shield Association Technology Evaluation Center (TEC) reported November 2007 that the evidence was not sufficient to permit conclusions as to whether computer-assisted navigation for total knee arthroplasty improves the net health outcome or is as beneficial as conventional alignment techniques.

Literature Review: Minimally invasive surgical techniques are difficult to evaluate in the scientific literature because of the multiple definitions describing the techniques, various approaches, and lack of reported long-term data. Comparing clinical outcomes across studies is difficult. Evidence in the medical literature evaluating minimally invasive approaches to knee replacement includes randomized, controlled trials; both retrospective and prospective case series; and comparative studies, in addition to published literature reviews. Most studies involve small patient populations and evaluate short term outcomes, ranging from the immediate post-operative period to approximately two and a half years following surgery (Dutton, et al., 2008; Kashyap and Ommeren, 2008; Juosponis, et al., 2008; McAllister and Stepanian, 2008; Schroer, et al., 2008, Huang, et al., 2007; Tashiro, et al., 2007; Kolisek, et al., 2007; Dalury and Dennis, 2005; Laskin, et al., 2005; Laskin, et al., 2004; Haas, et al., 2004; Muller, et al., 2004; Tria and Coon, 2003). Long-term health benefits are yet to be demonstrated and few studies have established a clear benefit from minimally invasive approaches of TKR.

When compared to traditional total knee replacement, studies have suggested that minimally invasive approaches result in faster functional recovery and improved knee range of motion (Bonutti, et al., 2010; Khanna, et al., 2009; Kashyap and Ommeren, 2008; Schroer, et al., 2008; Huang, et al., 2007; Tashiro, et al., 2007; Haas, et al., 2004; Muller, et al., 2004; Tria and Coon, 2003). However, these results are not consistently reported. The results of some studies suggest short term functional outcomes are comparable or not significantly different when compared to standard TKR (Karachalios, et al., 2008; Lüring, et al., 2008; McAllister and Stepanian, 2008; Kolisek, et al., 2007; Dalury and Dennis, 2005; Bonutti, et al., 2004).

Minimally invasive surgery is also associated with a learning curve and longer operative times for MIS TKR have been reported when compared to the standard approach (Khanna, et al., 2009; Karachalios, et al., 2008; Kolisek, et al., 2007; Tashiro, et al., 2007; Tria and Coon, 2003). Increased length of surgery may lead to a higher rate of complications in some patients (e.g., thromboembolism, infection). Whitehead (2006) reported that recent efforts to shorten the incision in total knee arthroplasty have added significant risk, but little benefit. In a trial comparing the effects of severity of preoperative varus deformity on radiograph accuracy for subjects who underwent MIS TKR, Niki et al. (2009) reported MIS techniques decreased radiographic accuracy of implant alignment, particularly in patients with severe varus deformity.

Additionally, decreased length of hospitalization stay has been reported for patients who have undergone MIS TKR (Shankar, 2006), while for other similar patient groups there have been reports of minimal differences in length of stay (Kolisek, et al. 2007). Comparison of perioperative outcomes such as shorter incision length, reduced tourniquet time and less intraoperative blood loss has been reported in the literature as well. Radiograph analysis of component positioning has also been performed in some studies with varying results; some suggest MIS TKR results in a high incidence of malpositioning (Huang, et al., 2007; Fisher, et al., 2003) while others report results are comparable to standard approaches with no significant differences in alignment (Bonutti, et al., 2010; Juosponis, et al., 2008; Kashyap and Ommeren, 2008; McAllister, et al., 2008; Chin, et al., 2007; Dalury and Dennis, 2005; Muller, et al., 2004).

Although theoretically computer navigation may improve accuracy of implant alignment, the clinical utility of this technology combined with minimally invasive techniques for TKR remains unknown. Studies evaluating navigation-assisted less invasive TKR or UKR compared to conventional TKR are mixed; while some suggest that the navigation assisted methods have fewer prosthetic alignment outliers (Jung, et al., 2010; Dutton, et al., 2008; Seon and Song, 2006) others indicate no distinct advantages (Karpman, et al., 2009; Bonutti, et al., 2008). Furthermore, published results have yet to demonstrate how improved alignment affects quality of life, function and implant longevity (ECRI, 2006).

Revision rates and implant survival rates vary. Barrack et al. (2009) reported the results of a consecutive series of first-time revision TKRs during a three year period (n=237), 44 subjects had an initial MIS TKR and 193 had a standard TKR. The authors noted the time to revision was significantly shorter for the MIS group compared to the standard TKR group (14.8 versus 80 months) and the authors were concerned regarding the high prevalence of MIS failures in a 24 month period of time. MIS knees were almost twice as likely to have instability or malrotation as a cause of failure.

There are a number of randomized controlled trials (RCTs) evaluating MIS TKR in the published scientific literature. One group of authors reported that although subjects who had MIS TKR had less pain after surgery and achieved and sustained better range of motion, the patients did not have a clinically important greater blood loss, component malpositioning, longer hospital stay or occurrence of complications (Varela-Egocheaga, et al., 2010). Pan et al. (2010) reported the results of a RCT comparing TKR outcomes using a mini-subvastus approach (n=35) to a standard approach (n=33). Average follow-up was 18 months; the patients who underwent the mini-subvastus approach had less blood loss and experienced less pain one day postoperatively. This same group also achieved active straight leg raising earlier, underwent less lateral retinacular releases, and had significantly better functional outcome and range of knee movement at nine months following surgery. At one year follow-up the author reported there was no significant difference between groups. Reduced access and visibility in the MIS group resulted in five technical errors on radiographic evaluation. In another RCT, Wulker et al. (2010) compared MIS TKR (n=66) to conventional TKR (n=68). At one year follow-up the authors noted there was no significant advantage to MIS. MIS was not associated with a reduction in blood loss, the duration of surgery was not significantly different, and almost identical range of motion was noted at time of discharge and at one year follow-up. At six months follow-up, Hernandez-Vaquero et al. (2010) also reported that MIS TKR showed no advantages compared to conventional TKR. In this study 26 subjects who underwent MIS TKR were matched to 36 who underwent conventional TKR. The authors reported that hospital stay was shorter for the MIS group, duration of surgery was longer, and blood loss in the immediate postoperative period was less. There were no statistically significant differences noted regarding alignment at the postoperative evaluation. However, at six months follow-up there were no differences found in range of motion, flexion or extension, level of pain, physical or mental SF-12 scores, or KSS scores,

MIS UKR has also been investigated and some authors have reported encouraging results (ODonnell, et al., 2010; Pandit, et al., 2010.) Nonetheless, some of the reported outcomes are mixed. Kort et al. (2007) reported the results of a prospective case series involving 154 unicompartmental knee replacements (n=132 patients) using a minimally invasive approach and a phase-3 Oxford mobile bearing device. The authors noted that 11% of the unicompartmental arthroplasties in all patients needed a revision, resulting in a survival rate of 89% during a 2-7 year follow-up interval. Hamilton and colleagues (2006) reported the results of a retrospective cohort of 221 consecutive patients treated with a minimally invasive, medial unicompartmental arthroplasty, compared to patients who underwent a standard arthrotomy and routine patellar eversion. The authors reported a total reoperation rate of 11.3% in the MIS group compared to 8.6% in the standard arthrotomy group. The rate of aseptic loosening in the MIS group was reported to be 3.7% compared to standard group of 1.0%.

The National Institute for Clinical Excellence (NICE) issued a procedural guidance regarding mini-incision surgery for total knee replacement (March, 2005). The Institute concluded that current evidence on the safety and efficacy of mini-incision surgery for total knee replacement does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. Furthermore, they concluded that more evidence is required on the long-term safety and efficacy of the procedure and that clinicians should submit data to the National Joint Registry (NICE, 2005).

Professional Societies/Organizations: The American Academy of Orthopaedic Surgeons (AAOS, 2003) guideline on minimally invasive surgery states, "The American Academy of Orthopaedic Surgeons believes that 'Minimally Invasive Surgery' for total joint replacement is a promising, but evolving surgical technique that requires additional scientific evidence to validate its short and long-term safety and effectiveness, in comparison to conventional joint replacement methods."

Advisory statements regarding minimally invasive and small incision joint replacement surgery by the American Association of Hip and Knee Surgeons (AAHKS, 2004; updated 2008) indicate that same or better long-term outcomes have not been validated with less invasive knee replacement surgery, and there is not a great deal of significant scientific proof to support its use at this time. Scientific evidence and rigorous evaluation of minimally

invasive joint arthroplasty techniques are needed before these techniques are recommended for more widespread clinical practice.

Unicondylar Interpositional Spacer (UniSpacer®)

The unicondylar interpositional spacer is a small minimally invasive device that is designed to fit between the natural bony structures of the knee and stays in place without screws or cement and allows preservation of the patient's bone. The device is proposed for relief of pain and improvement of joint stability; in patients for whom osteotomy is contraindicated due to early opposite compartment disease or poor range of motion; and for patients considered too young, too heavy or too active for total knee arthroplasty.

U.S. Food and Drug Administration (FDA): The UniSpacer was determined to be substantially equivalent to previously approved knee prostheses and was granted marketing approval by the FDA via the 501(k) process on January 4, 2001. The UniSpacer is intended for uncemented use in the treatment of moderate degeneration of the medial compartment of the knee (grade III–IV chondromalacia) with no more than minimal degeneration (grade I–II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments. This device is an implantable prosthetic device described as a cobalt chromium, asymmetric, kidney-shaped device, designed to mimic the shape of the medial tibial condyle.

According to the 510(k) summary, the UniSpacer was developed as an alternative to arthroscopy, high tibial osteotomy and knee arthroplasty for situations where limited degeneration/joint destruction exists. The treatment allows for placement of the metallic spacer into the joint space above the affected medial tibial plateau. The femur articulates against the polished, curved surface of the device. It is intended to be used without cement and is held in place by its geometry and the surrounding soft tissue structures. The surgical procedure to implant the device takes place in two stages. The posterior horn of the meniscus is debrided and resected arthroscopically. The device is then inserted into the joint space above the affected medial tibial plateau via open surgical implantation. Similar devices that have received more recent FDA 510(k) approval include but are not limited to the Knee Interpositional Spacer (Osteoimplant Technology, Hunt Valley, MD), the Knee Interpositional Mini-Repair System (Imaging Therapeutics, Inc., San Mateo, CA) and the custom manufactured ConforMIS iForma™ (ConformMIS Inc., Burlington, MA).

Literature Review: There is a paucity of evidence in the published scientific literature evaluating the UniSpacer and other similar devices. Studies comparing metallic tibial hemiarthroplasty with the UniSpacer to conservative treatment or traditional surgical approaches of osteotomy, unicompartmental arthroplasty and total knee arthroplasty are not available. Bailie et al. (2008) reported the results of prospective clinical trial involving 18 patients who underwent insertion of a UniSpacer knee implant for isolated medial compartment osteoarthritis. Patients were followed for an average of 17.1 months. Early results were unsatisfactory with 17 patients reporting persistent pain within the first three to six months following surgery. Twelve patients required further intervention such as non-steroidal anti-inflammatory medications, intra-articular injections, manipulation under anesthesia and revision surgery. A total of eight patients required revision within two years; six patients required conversions to unicompartmental or TKR, two required a larger spacer. Twelve patients who retained the UniSpacer had an average pain level that was 30% that of the mean pre-operative level.

Sisto and Mitchell (2005) reported the experience of one surgeon with UniSpacer arthroplasty in the treatment of isolated medial compartment arthritis of the knee. From April through November 2002, 37 UniSpacer arthroplasties were performed in 34 patients with a median age of 55. A prior arthroscopic meniscectomy had been performed in 12 patients. The mean preoperative Knee Society function score was 60 points (range, 40–80 points) and the mean preoperative Knee Society objective score was 62 points (range, 40–76 points). At a mean follow-up of 26 months, there were no excellent, 10 good, 15 fair and 12 poor results. The mean postoperative total function score was 69 points (range 40–82 points), and the mean Knee Society objective score was 72 points (range, 45–88 points). Six of the 12 poor results were in knees that had dislocation of the UniSpacer. All 12 knees were revised to a total knee arthroplasty. The authors noted that, based on this experience, they do not recommend UniSpacer arthroplasty for the treatment of degenerative arthritis of the medial compartment of the knee.

Hallock and Fell (2003) published results of one- and two-year data of 71 UniSpacer implants in 67 patients (four patients had bilateral implants). The mean age and weight of the patients were 54 years and 207 pounds, respectively. After one year, 63 patients (66 knees) continued to have the implant in place. All knees were evaluated using the Knee Society clinical rating system, Lysholm scoring scale, radiographic limb alignment and

range of motion. Mean scores after one and two years showed improvement in all measures. Five implants were revised to total knee arthroplasties, and 10 implants were revised to another UniSpacer implant. In the authors opinion early results suggest the UniSpacer is a viable treatment option for osteoarthritis in the younger patient. Limitations of this study involved small numbers of patients and lack of long-term outcome data.

The California Technology Assessment Forum (CTAF) (Tice, 2003) reported that no published studies are available to assess the safety and efficacy of the UniSpacer device. Surgical placement of knee joint spacer devices requires evaluations in controlled trials to determine safety and efficacy before widespread adoption can be recommended. Surgical placement of a knee joint spacer for the treatment of osteoarthritis did not meet the CTAF technology assessment criteria.

Summary

Total knee replacement (TKR) and unicompartmental knee replacement (UKR), for advanced medial, lateral, or patellofemoral compartment joint disease (e.g., end stage arthritis), is supported with sufficient clinical evidence in the published scientific literature as safe and effective in relieving pain and improving joint function and mobility. Failure of a total knee replacement may necessitate revision, which has been successful for many individuals. There is insufficient evidence to support safety, efficacy, and improved long-term outcomes for bicompartmental or bi-unicompartmental knee replacement. The clinical benefit of a minimally invasive surgical approach for total knee replacement has not yet been proven in the medical literature. There is also a lack of evidence in the published medical literature supporting a unicondylar interpositional spacer device, such as the UniSpacer. While this device may provide short-term improvement for osteoarthritis of the medial or lateral knee compartment, long-term effectiveness and durability of the device is not known. Overall, further well-designed clinical studies are required to document long-term effectiveness, durability and improvement in functional outcomes with use of these technologies.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

TOTAL KNEE REPLACEMENT

Covered when medically necessary:

CPT [®] * Codes	Description
27445	Arthroplasty, knee, hinge prosthesis (eg, Walldius type)
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)

ICD-9-CM Diagnosis Codes	Description
696.0	Psoriatic arthritis
714.0	Rheumatoid arthritis
715.16	Osteoarthritis, localized, primary, lower leg
715.26	Osteoarthritis, localized, secondary, lower leg
715.36	Osteoarthritis, localized, not specified whether primary or secondary, lower leg
715.96	Osteoarthritis, unspecified whether generalized or localized, lower leg
716.16	Traumatic arthropathy, lower leg
716.56	Unspecified polyarthropathy or polyarthritis, lower leg
716.66	Unspecified monoarthritis, lower leg
716.86	Other specified arthropathy, lower leg
716.96	Unspecified arthropathy, lower leg
717.7	Chondromalacia of patella
718.46	Contracture of lower leg joint

718.56	Ankylosis of lower leg joint
718.86	Other joint derangement, not elsewhere classified, lower leg
719.46	Pain in joint, lower leg
719.56	Stiffness of joint, not elsewhere classified, lower leg
719.96	Unspecified disorder of joint, lower leg
726.60 – 726.69	Enthesopathy of knee
733.40	Aseptic necrosis of bone, unspecified
733.43	Aseptic necrosis of bone, Medial femoral condyle
733.49	Aseptic necrosis of bone, other
822.0– 822.1	Fracture of patella
836.3	Closed dislocation of patella
836.4	Open dislocation of patella

REVISION TOTAL KNEE REPLACEMENT

Covered when medically necessary:

CPT^{®*} Codes	Description
27486	Revision of total knee arthroplasty, with or without allograft; one component
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component

ICD-9-CM Diagnosis Codes	Description
719.46	Pain in joint, lower leg
822.0– 822.1	Fracture of patella
836.3	Closed dislocation of patella
836.4	Open dislocation of patella
996.4-996.49	Complications of internal orthopedic device, implant, and graft
996.66	Infection and inflammation due to internal joint prosthesis
996.77	Other complications of internal (biological) (synthetic) prosthetic device, implant, and graft, due to internal joint prosthesis
V43.65	Organ or tissue replaced by other means, joint, knee

UNICOMPARTMENTAL KNEE REPLACEMENT

Covered when medically necessary:

CPT^{®*} Codes	Description
27438	Arthroplasty, patella; with prosthesis
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment

ICD-9-CM Diagnosis Codes	Description
696.0	Psoriatic arthritis
715.16	Osteoarthritis, localized, primary, lower leg
715.26	Osteoarthritis, localized, secondary, lower leg
715.36	Osteoarthritis, localized, not specified whether primary or secondary, lower leg
715.96	Osteoarthritis, unspecified whether generalized or localized, lower leg
716.16	Traumatic arthropathy, lower leg
716.56	Unspecified polyarthropathy or polyarthritis, lower leg

716.66	Unspecified monoarthritis, lower leg
716.86	Other specified arthropathy, lower leg
716.96	Unspecified arthropathy, lower leg
717.7	Chondromalacia of patella
718.46	Contracture of lower leg joint
718.56	Ankylosis of lower leg joint
718.86	Other joint derangement, not elsewhere classified, lower leg
719.46	Pain in joint, lower leg
719.56	Stiffness of joint, not elsewhere classified, lower leg
719.96	Unspecified disorder of joint, lower leg
726.60 – 726.69	Enthesopathy of knee
733.40	Aseptic necrosis of bone, unspecified
733.49	Aseptic necrosis of bone, other
822.0– 822.1	Fracture of patella
836.3	Closed dislocation of patella
836.4	Open dislocation of patella

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures; image-less (List separately in addition to code for primary procedure)
0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure)
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (List separately in addition to code for primary procedure)

ICD-9-CM Diagnosis Codes	Description
	All Codes

Experimental, investigational, unproven or not covered when used to report a unicondylar interpositional spacer (e.g., UniSpacer), minimally invasive knee arthroplasty, or bicompartamental/bi-unicompartamental arthroplasty.

CPT* Codes	Description
27599	Unlisted procedure, femur or knee

ICD-9-CM Diagnosis Codes	Description
	All Codes

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	5/15/2008	0347	Knee Arthroplasty/Replacement
Great-West Healthcare	9/19/2007	07.356.01	Knee Arthroplasty, Bi-Compartmental (The Journey DEUCE Knee System)

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