



CIGNA MEDICAL COVERAGE POLICY

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Subject **Knee Arthroplasty/Replacement**

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Hyperlink to Related Coverage Policies

Computer-Assisted Guidance for Orthopedic Surgery

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Coverage Policy

CIGNA covers a total knee replacement as medically necessary when there is radiographic evidence of advanced joint disease and BOTH of the following conditions are met:

- persistent 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

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

- recurrent disabling 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
- infection
- periprosthetic fractures

CIGNA covers a unicompartmental (i.e., partial) knee replacement for the medial or lateral compartment as medically necessary when ALL of the following conditions are met:

- severe osteoarthritis is 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

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

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

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 and computer-aided navigation. Other technologies such as custom made knee replacement prostheses (e.g., Custom Fit Knee™ Replacement [OtisMed Corp., Alameda, CA]) 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 have yet to be demonstrated.

Total Knee Replacement (TKR)

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). 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)/Medial or Lateral Compartment

Unicompartmental knee replacement has been proposed as an alternative to TKR for patients with disease limited to a single compartment (i.e., medial or lateral), 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 main muscle controlling the knee (American Academy of Orthopaedic Surgeons [AAOS], 2006). The surgery may be performed through standard exposure or utilizing minimally invasive surgery with modified instruments.

UKA is considered to be as safe and effective as TKA and high tibial osteotomy (Griffin et al., 2007). 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). 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

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. A patellofemoral knee replacement, similar to a unicompartmental replacement, replaces only the worn articular surface underneath the patella and its articulating trochlear surface.

While some results have been favorable, isolated patellofemoral replacement is considered controversial; evidence in the published scientific literature does not lead to strong conclusions regarding efficacy. The reported results for complications and revision vary among studies; however some authors do report results demonstrating improved pain, function and mobility. Authors have proposed the use of custom-designed patellofemoral prosthetic devices versus off-the-shelf designs as a method of improving clinical outcomes. Patient selection criteria have not been clearly defined and long-term device durability comparable to TKR has yet to be proven. Patellofemoral arthroplasty is associated with progression of OA in surrounding compartments and revision to TKR. 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.

Literature Review: In several of the early published studies (Argenson, et al., 2005; Merchant, 2004; Kooijman, et al., 2003; Smith, et al., 2002; Tauro, et al., 2001; de Winter et al., 2001) overall follow-up ranged from mean duration of 3.75 years to 17 years. Various scales were used to assess clinical outcomes, and included the ADL scale, Knee Society scores, follow-up radiographs, modified Hungerford and Kenna knee score, the Bristol Knee score, and subjective questionnaires making comparisons difficult. However, good and excellent results ranged from 45% to 93% across these specific studies.

Revision rates and survivorship also varied among earlier studies. 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 ± .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.

More recent studies indicate that patellofemoral arthroplasty for isolated patellofemoral arthritis of the knee remains controversial. Some of the literature involves patient populations that overlap. Many of the available studies are in the form of retrospective and prospective case series and lacks randomized controlled trials (Meding, et al., 2007; Ackroyd, et al., 2007; Sisto and Sarin, 2006; Ackroyd and Chir, 2005; Leadbetter, et al., 2005). Meding et al. (2007) retrospectively compared the outcomes of TKR versus patellofemoral replacement in younger patients. The study was a retrospective review of 27 patients, average age of 52 years, with an average follow-up of 6.2 years. Outcomes were compared to historical data from patients who underwent patellofemoral arthroplasty. The authors reported that there were no differences in clinical scores of the study group when compared to the matched group. However, complication rates were lower for the TKR group.

Ackroyd et al. (2007) reported the results of a three-year prospective series of patients treated with patellofemoral arthroplasty (n=85 patients, 109 knees). The mean follow-up using the Bristol pain and knee, Melbourne patellar, and Oxford knee scores was 5.2 years. Eighty three knees were available for assessment. The functional outcome scores showed improvement for pain, patellar function and knee function. In 25 patients progression of osteoarthritic disease was noted of either the medial or lateral compartments of the tibiofemoral joint. Four of these required revision during the first five years which resulted in a survivorship of 95%. After five years, 11 knees required revision. There were no cases of loosening of the prosthesis reported.

Sisto and Sarin (2006) conducted a retrospective case series evaluating the clinical results of a patellofemoral arthroplasty utilizing a custom-designed prosthesis (i.e., Kinemad) in patients under age 50. Twenty-five patellofemoral arthroplasties were performed in 22 patients with isolated patellofemoral arthritis of the knee (on both sides of the articulation, as noted by the authors). All patients were evaluated using the Knee Society functional and objective rating scales. A score of > 90 points was considered by the authors to be excellent; a score of 80–90 was considered a good outcome. The authors reported 18 excellent and seven good results at a mean of 73 months postoperatively. The mean Knee Society functional score was 89 points (preoperative score was 49 points), and the mean Knee Society objective score was 91 points (preoperative score was 52 points). The authors acknowledged the results of the study compared favorably with those of TKR performed in similar but older groups of patients. While the custom patellofemoral arthroplasty appeared to be safe and effective in this study, the study is limited by short-term follow-up and small population.

Ackroyd and Chir (2005) conducted a prospective review of 306 patellofemoral arthroplasties (n=240). Eight-month follow-up was reported for 170 knees; two-year follow-up was reported for treatment of 124 knees; and five-year follow-up was reported for treatment of 33 knees. The outcome assessment tools included the Bristol Pain Score, Melbourne patellofemoral score, and the Oxford Knee Score. At five years follow-up, there was no deterioration in pain or function. Sixteen patients had early complications that included slight maltracking, distal soft tissue realignment, and patella alta and neuromuscular imbalance, slow development of range of motion, all of which according to the authors were resolved satisfactorily. There were no late complications reported although the long-term problem was noted to be disease progression of the tibiofemoral joint which occurred in 16 knees (5%), 11 of which required a revision TKR (3.6%). The median Bristol pain score improved from 15 points (out of 40 maximum) to 35 at two years and 38 at five years. The mean range of motion improved at five years from 114° to 120°. The median Melbourne score improved from 10 points (out of 30 maximum) to 26 points at two years, and 27 points at five years. The median Oxford score improved from 19 points (out of 48 maximum) to 38 at two years, and 40 at five years. Persistent anterior knee pain was reported in 14 knees. While the results of this study support improvement in pain, range of movement and function, it is limited by relatively short-term follow-up (i.e., five years) and lack of comparison groups.

Leadbetter and colleagues (2005) published a systematic review that evaluated the results of patellofemoral arthroplasty published in 12 studies between 1979 and 2005. Overall, reoperation was done on 24% of all knees treated. The mean duration of follow-up was 5.7 years. Revision surgery, (rates which ranged between 5 and 28%), was most often related to extensor malalignment with prosthetic instability, progression of arthritis, prosthetic malpositioning, mechanical prosthetic-related symptoms, and prosthetic type. The overall patient age range was 19 to 90 years. The highest failure rates were in patients with progression of osteoarthritis in other

compartments or persistence of congenital or surgically uncorrected malalignment. In the author's opinion, successful surgical intervention included selecting patients with proper diagnosis, surgeon experience with patellofemoral realignment and absence of tricompartmental arthritis. Age limitations for patellofemoral arthroplasty were not clearly defined. The authors recommended extensive evaluation of other compartments preoperatively to identify the isolated patellofemoral treatment group. Although the reported outcomes are encouraging, the review is limited by the small number of cases available, the small number of patient populations, and limited data as some studies had significant loss to follow-up. In addition, none of the studies reviewed consisted of randomized trials and there were no Level I or Level II studies with a comparison to TKR.

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.

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

In 2008 Confalonieri et al. reported the results of a comparison of 22 patients who underwent bi-unicompartmental 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 bicompartmental prosthetic device, Rolston and colleagues (2007) reported the results of a series of 95 patients who were implanted with the bicompartmental 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-unicompartmental knee replacement performed on 24 knees with bicompartmental 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 unicompartmental 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.

Minimally Invasive Techniques

Standard surgical approaches to TKR allow for greater visibility and safe mobilization of the tissues. Minimally invasive approaches to TKR 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., unicompartmental 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. 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 (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 (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 (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 "Recent efforts to shorten the incision in total knee arthroplasty have added significant risk, but little benefit."

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 (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 compared to conventional TKR are mixed; while some suggest that the navigation assisted methods have fewer prosthetic alignment outliers (Dutton, et al., 2008; Seon and Song, 2006) others indicate no distinct advantages (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. 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. 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.

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.

Baillie 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.

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 medial or lateral compartment joint disease is supported with sufficient clinical evidence in the published scientific literature as safe and effective in relieving pain and improving joint function. 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 unicompartmental patellofemoral replacement, bicompartamental 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.

Covered when medically necessary:

CPT [®] * Codes	Description
27445	Arthroplasty, knee, hinge prosthesis (eg, Walldius type)
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
27486	Revision of total knee arthroplasty, with or without allograft; one component
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component

ICD-9-CM Diagnosis Codes	Description
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
717.6	Internal derangement of knee, loose body in knee
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
822.0– 822.1	Fracture of patella
836.3	Closed dislocation of patella
836.4	Open dislocation of patella
V43.65	Organ or tissue replaced by other means, joint, knee

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)

20986	Computer-assisted surgical navigational procedure for musculoskeletal procedures; with image guidance based on intraoperatively obtained images (eg, fluoroscopy, ultrasound) (List separately in addition to code for primary procedure) (Deleted 12/31/08)
20987	Computer-assisted surgical navigational procedure for musculoskeletal procedures; with image guidance based on preoperative images (List separately in addition to code for primary procedure) (Deleted 12/31/08)
27438	Arthroplasty, patella; with prosthesis
27599 [†]	Unlisted procedure, femur or knee
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)

[†]**Note:** Experimental/ investigational/ unproven/not covered when used to report a unicondylar interpositional spacer (e.g., UniSpacer) or any minimally invasive knee arthroplasty procedure or bicompartamental/bi-unicompartamental arthroplasty.

*Current Procedural Terminology (CPT[®]) ©2008 American Medical Association: Chicago, IL.

References

1. Ackroyd CE, Chir B. Development and early results of a new patellofemoral arthroplasty. Clin Orthop Relat Res. 2005 Jul;(436):7-13.
2. Ackroyd CE, Newman JH, Evans R, Eldridge JD, Joslin CC. The Avon patellofemoral arthroplasty: five-year survivorship and functional results. J Bone Joint Surg Br. 2007 Mar;89(3):310-5.
3. American Academy of Orthopaedic Surgeons. AAOS clinical guideline on osteoarthritis of the knee (phase II). Rosemont (IL): American Academy of Orthopaedic Surgeons; 2003. 15 p.
4. American Academy of Orthopaedic Surgeons. Total knee replacement. Patient education library. January 2006. Reviewed and updated August 2007. Accessed March 9, 2009. Available at URL address: http://orthoinfo.aaos.org/fact/thr_report.cfm?Thread_ID=513&topcategory=Knee
5. American Academy of Orthopaedic Surgeons (AAOS). Minimally invasive total knee replacement. Reviewed and updated August 2007. Copyright ©1995-2007 by the American Academy of Orthopaedic Surgeons. Accessed March 9, 2009. Available at URL address: http://orthoinfo.aaos.org/topic.cfm?topic=A00405&return_link=0
6. American Association of Hip and Knee Surgeons. Minimally invasive surgery. Patient advisory statement. July 2004. Revised January 2008. Accessed March 9, 2009. Available at URL address: <http://www.aaos.org/Research/guidelines/guide.asp>
7. Argenson JN, Flecher X, Parratte S, Aubaniac JM. Patellofemoral arthroplasty: an update. Clin Orthop Relat Res. 2005 Nov;440:50-3.
8. Ault A. Minimally invasive knee replacement comparable to conventional surgery. Medscape Medical News. 2004.
9. Bailie AG, Lewis PL, Brumby SA, Roy S, Paterson RS, Campbell DG. The Unispace knee implant: early clinical results. J Bone Joint Surg Br. 2008 Apr;90(4):446-50.

10. Berend KR, Lombardi AV Jr, Adams JB. Obesity, young age, patellofemoral disease, and anterior knee pain: identifying the unicompartmental arthroplasty patient in the United States. *Orthopedics*. 2007 May;30(5 Suppl):19-23.
11. Berger RA, Meneghini RM, Jacobs JJ, Sheinkop MB, Della Valle CJ, Rosenberg AG, Galante JO. Results of unicompartmental knee arthroplasty at a minimum of ten years of follow-up. *J Bone Joint Surg Am*. 2005 May;87(5):999-1006.
12. Berger RA, Nedeff DD, Barden RM, Sheinkop MM, Jacobs JJ, Rosenberg AG, et al. Unicompartmental knee arthroplasty: clinical experience at 6- to 10-year followup. *Clin Orthop Relat Res*. 1999 Oct;(367):50-60.
13. Bert JM. Unicompartmental knee replacement. *Orthop Clin N Am*. 2005 Oct;36(4):513-22.
14. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Computer-Assisted Navigation for Total Knee Arthroplasty. November 2007. Accessed March 9, 2009. Available at URL address: http://www.bcbs.com/betterknowledge/tec/vols/22/22_10.html
15. Bonutti PM, Dethmers DA, McGrath MS, Ulrich SD, Mont MA. Navigation did not improve the precision of minimally invasive knee arthroplasty. *Clin Orthop Relat Res*. 2008 Nov;466(11):2730-5. Epub 2008 Jul 10.
16. Bonutti PM, Mont MA, Kester MA. Minimally invasive total knee arthroplasty: a 10-feature evolutionary approach. *Orthop Clin North Am*. 2004 Apr;35(2):217-26.
17. Bonutti PM, Mont MA, McMahan M, Ragland PS, Kester M. Minimally invasive total knee arthroplasty. *J Bone Joint Surg Am*. 2004 Jan;86-A Suppl 2:26-32.
18. Borus T, Thornhill T. Unicompartmental knee arthroplasty. *J Am Acad Orthop Surg*. 2008 Jan;16(1):9-18.
19. Canadian Agency for Drugs and Technologies in Health (CADTH). Gender solution: Knee replacement implants for women. Health technology assessment. Issue 8, January 2008. Accessed March 10, 2009. Available at URL: <http://cadth.ca/index.php/en/hta/reports-publications/health-technology-update/health-tech-update-issue8/gender>
20. Cartier P, Sanouillier JL, Khefacha A. Long-term results with the first patellofemoral prosthesis. *Clin Orthop Relat Res*. 2005 Jul;(436):47-54.
21. Chin PL, Foo LS, Yang KY, Yeo SJ, Lo NN. Randomized controlled trial comparing the radiologic outcomes of conventional and minimally invasive techniques for total knee arthroplasty. *J Arthroplasty*. 2007 Sep;22(6):800-6. Epub 2007 Apr 20.
22. Clarke HD, Scott WN. Total knee arthroplasty. Section N Knee Replacement in the Recreational Athlete. In: DeLee: DeLee and Drez's Orthopaedic Sports Medicine, 2nd ed. Copyright © 2003 Saunders. Ch 28.
23. Confalonieri N, Manzotti A. Tissue-sparing surgery with the bi-unicompartmental knee prosthesis: retrospective study with minimum follow-up of 36 months. *J Orthopaed Traumatol* 2006 Jun;7(2):108-12.
24. Confalonieri N, Manzotti A, Cerveri P, De Momi E. Bi-unicompartmental versus total knee arthroplasty: a matched paired study with early clinical results. *Arch Orthop Trauma Surg*. 2008 Aug 12.
25. Crockerall JR, Guyton JL. Arthroplasty of ankle and knee. In: Canale TS, editor. *Campbell's operative orthopaedics*, 10th ed., Chapter 6. Copyright ©2003, Mosby, Inc.
26. Dabov G, Perez EA. Miscellaneous nontraumatic disorders. Osteoarthritis. In: Canale T, editor. *Campbell's operative orthopaedics*. 10th ed. St. Louis, MO: Mosby, Inc.; 2003. Ch. 25.
27. Dalury DF, Dennis DA. Mini-incision total knee arthroplasty can increase the risk of component malalignment. *Clin Orthop Relat Res*. 2005 Nov;440:77-81.

28. Delanois RE, McGrath MS, Ulrich SD, Marker DR, Seyler TM, Bonutti PM, Mont MA. Results of total knee replacement for isolated patellofemoral arthritis: when not to perform a patellofemoral arthroplasty. *Orthop Clin North Am.* 2008 Jul;39(3):381-8, vii.
29. Donell ST, Glasgow MM. Isolated patellofemoral osteoarthritis. *Knee.* 2007 Jun;14(3):169-76. Epub 2007 Jan 11.
30. Dutton AQ, Yeo SJ, Yang KY, Lo NN, Chia KU, Chong HC. Computer-assisted minimally invasive total knee arthroplasty compared with standard total knee arthroplasty. A prospective, randomized study. *J Bone Joint Surg Am.* 2008 Jan;90(1):2-9.
31. ECRI Institute. Health Technology Forecast [database online]. Plymouth Meeting (PA): ECRI; [Published 11/26/2008]. Minimally invasive knee arthroplasty. Available at URL address: <http://www.ecri.org>
32. Fisher DA, Watts m, Davis KE. Implant position in knee surgery: a comparison of minimally invasive, open unicompartmental, and total knee arthroplasty. *J Arthroplasty.* 2003 Oct;18(7 Suppl 1):2-8.
33. Griffin T, Rowden N, Morgan D, Atkinson R, Woodruff P, Maddern G. Unicompartmental knee arthroplasty for the treatment of unicompartmental osteoarthritis: a systematic study. *ANZ J Surg.* 2007 Apr;77(4):214-21.
34. Haas SB, Cook S, Beksac B. Minimally invasive total knee replacement through a mini midvastus approach: a comparative study. *Clin Orthop Relat Res.* 2004 Nov;(428):68-73.
35. Haas SB, Manitta MA, Burdick P. Minimally invasive total knee arthroplasty: the mini midvastus approach. *Clin Orthop Relat Res.* 2006 Nov;452:112-6.
36. Hallock RH, Fell BM. Unicompartmental tibial hemiarthroplasty: early results of the UniSpacer knee. *Clin Orthop.* 2003 Nov;(416):154-63.
37. Hallock RH. The UniSpacer: a treatment alternative for the middle-aged patient. *Orthop Clin North Am.* 2005 Oct;36(4):505-12.
38. Hamilton WG, Collier MB, Tarabee E, McAuley JP, Engh CA Jr, Engh GA. Incidence and reasons for reoperation after minimally invasive unicompartmental knee arthroplasty. *J Arthroplasty.* 2006 Sep;21(6 Suppl 2):98-107.
39. Huang HT, Su JY, Chang JK, Chen CH, Wang GJ. The early clinical outcome of minimally invasive quadriceps-sparing total knee arthroplasty: report of a 2-year follow-up. *J Arthroplasty.* 2007 Oct;22(7):1007-12.
40. Juosponis R, Tarasevicius S, Smailys A, Kalesinskas RJ. Functional and radiological outcome after total knee replacement performed with mini-midvastus or conventional arthrotomy: controlled randomised trial. *Int Orthop.* 2008 Jul 25. [Epub ahead of print].
41. Kane RL, Saleh KJ, Wilt TJ, Bershadsky B, Cross WW III, MacDonald RM, et al.; Minnesota Evidenced-Based Practice Center. Total knee replacement [evidence report/technology assessment No. 86]. Pub. No. 04-E006-1. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); 2003 Nov.
42. Kashyap SN, van Ommeren JW. Clinical experience with less invasive surgery techniques in total knee arthroplasty: a comparative study. *Knee Surg Sports Traumatol Arthrosc.* 2008 Jun;16(6):544-8. Epub 2008 Mar 26.
43. Kolisek FR, Bonutti PM, Hozack WJ, Purtill JJ, Sharkey PF, Zelicof SB, et al. Multi-center study: comparison of standard to minimally invasive total knee arthroplasty. Presented at American Academy of Orthopaedic Surgeons (AAOS) 2005 Annual Meeting; 2005 Feb 23-27; Washington, DC. Accessed March 22, 2006. Available at URL address: <http://www.aaos.org/wordhtml/anmt2005/scipro/070.htm>

44. Kolisek FR, Bonutti PM, Hozack WJ, Purtill J, Sharkey PF, Zelicof SB, et al. Clinical experience using a minimally invasive surgical approach for total knee arthroplasty: early results of a prospective randomized study compared to a standard approach. *J Arthroplasty*. 2007 Jan;22(1):8-13.
45. Kooijman HJ, Driessen AP, van Horn JR. Long-term results of patellofemoral arthroplasty. A report of 56 arthroplasties with 17 years of follow-up. *J Bone Joint Surg Br*. 2003 Aug;85(6):836-40.
46. Koopman WJ, Moreland LW. *Arthritis and allied conditions*. 15th ed. Lippincott Williams & Wilkins. 2005.
47. Kort NP. Unicompartmental knee arthroplasty. eMedicine. Orthopedic surgery. Knee. Updated January 5, 2007. Accessed March 9, 2009. Available at URL address: <http://www.emedicine.com/orthoped/topic631.htm>
48. Kort NP, van Raay JJ, Cheung J, Jolink C, Deutman R. Analysis of Oxford medial unicompartmental knee replacement using the minimally invasive technique in patients aged 60 and above: an independent prospective series. *Knee Surg Sports Traumatol Arthrosc*. 2007 Nov;15(11):1331-4. Epub 2007 Aug 8.
49. Laskin RS. Mini-incision: occasionally desirable, rarely necessary in opposition. *J Arthroplasty*. 2006 Jun;21(4 Suppl 1):19-21.
50. Laskin RS, Beksac B, Phongjunakorn A, Pittors K, Davis J, Shim JC, et al. Minimally invasive total knee replacement through a mini-midvastus incision: an outcome study. *Clin Orthop Relat Res*. 2004 Nov;(428):74-81.
51. Laskin RS. Minimally invasive total knee arthroplasty. *Clin Orthop Relat Res*. 2005 Nov;440:54-9.
52. Leadbetter WB, Kolisek FR, Levitt RL, Brooker AF, Zietz P, Marker DR, Bonutti PM, Mont MA. Patellofemoral arthroplasty: a multi-centre study with minimum 2-year follow-up. *Int Orthop*. 2008 Dec 5. [Epub ahead of print].
53. Leadbetter WB, Ragland PS, Mont MA. The appropriate use of patellofemoral arthroplasty: an analysis of reported indications, contraindications, and failures. *Clin Orthop Relat Res*. 2005 Jul;(436):91-9.
54. Leadbetter WB, Seyler TM, Ragland PS, Mont MA. Indications, contraindications, and pitfalls of patellofemoral arthroplasty. *J Bone Joint Surg Am*. 2006 Dec;88 Suppl 4:122-37.
55. Loeser JD, Butler SH, Chapman CR, Turk DC, editors. Painful disorders of the knee joint. In: Bonica's management of pain, 3rd ed. Lippincott Williams and Wilkins. 2001.
56. Lonner JH. Patellofemoral arthroplasty. *J Am Acad Orthop Surg*. 2007 Aug;15(8):495-506.
57. Lonner JH, Jasko JG, Booth RE Jr. Revision of a failed patellofemoral arthroplasty to a total knee arthroplasty. *J Bone Joint Surg Am*. 2006 Nov;88(11):2337-42.
58. Lotke PA, Lonner JH, Nelson CL. Patellofemoral arthroplasty: the third compartment. *J Arthroplasty*. 2005 Jun;20(4 Suppl 2):4-6.
59. Lüring C, Beckmann J, Haiböck P, Perlick L, Grifka J, Tingart M. Minimal invasive and computer assisted total knee replacement compared with the conventional technique: a prospective, randomised trial. *Knee Surg Sports Traumatol Arthrosc*. 2008 Oct;16(10):928-34. Epub 2008 Jul 17.
60. McAllister CM, Stepanian JD. The impact of minimally invasive surgical techniques on early range of motion after primary total knee arthroplasty. *J Arthroplasty*. 2008 Jan;23(1):10-8.
61. Meek RMD, Masri BA, Duncan CP. Minimally invasive unicompartmental knee replacement: rationale and correct indications. *Orthop Clin North Am*. 2004 Apr;35(2):191-200.

62. Merchant AC. Early results with a total patellofemoral joint replacement arthroplasty prosthesis. *J Arthroplasty*. 2004 Oct;19(7):829-36.
63. Minimally invasive and small incision joint replacement surgery: what surgeons should consider [physician advisory statement]. Park Ridge, IL: American Association of Hip and Knee Surgeons (AAHKS); 2004 Jul. Accessed April 10, 2007. Available at URL address: <http://www.aaos.org/Research/guidelines/guide.asp>
64. Minimally invasive knee surgery [guideline]. Rosemont, IL: American Academy of Orthopaedic Surgeons (AAOS); 2003. Last modified 2003 Jun 18. Accessed March 22, 2006. Available at URL address: <http://www.aaos.org/wordhtml/research/guidelin/guide.htm>
65. Minimally invasive total knee replacement. Rosemont, IL: American Academy of Orthopaedic Surgeons (AAOS); 2005 Feb. Accessed April 10, 2007. Available at URL address: http://www.orthoinfo.org/fact/thr_report.cfm?Thread_ID=472&topcategory=Knee
66. Muller PE, Pellengahr C, Witt M, Kircher J, Refior HJ, Jansson V. Influence of minimally invasive surgery on implant positioning and the functional outcome for medial unicompartmental knee arthroplasty. *J Arthroplasty*. 2004 Apr; 19(3):296-301.
67. Murray DW, Goodfellow JW, O'Connor JJ. The Oxford medial unicompartmental arthroplasty: a ten-year survival study. *J Bone Joint Surg Br*. 1998 Nov;80(6):983-9.
68. National Institute for Clinical Excellence (NICE). Mini-incision surgery for knee replacement. *Interventional procedure guidance 117*. March 2005. Accessed March 9, 2009. Available at URL address: <http://www.nice.org.uk/search/guidancesearchresults.jsp?keywords=knee+surgery&searchType=guidance>
69. National Institute for Clinical Excellence (NICE). Insertion of individually magnetic resonance imagin-designed unicompartmental interpositional implant in osteoarthritis of the knee. *Interventional procedure guidance 705*. Accessed March 9, 2009. Available at URL address: <http://www.nice.org.uk/guidance/index.jsp?action=download&o=43362>
70. National Institutes of Health. NIH Consensus Development Conference on Total Knee Replacement; 2003 Dec 8-10. Final statement. Accessed March 10, 2009. Available at URL address: <http://consensus.nih.gov/2003/2003TotalKneeReplacement117html.htm>
71. Newman JH, Ackroyd CE, Shah NA. Unicompartmental or total knee replacement? Five-year results of a prospective, randomised trial of 102 osteoarthritic knees with unicompartmental arthritis. *J Bone Joint Surg Br*. 1998 Sep;80(5):862-5.
72. Richmond JC. Surgery for osteoarthritis of the knee. *Med Clin North Am*. 2009 Jan;93(1):213-22, xii.
73. Rolston L, Bresch J, Engh G, Franz A, Kreuzer S, Nadaud M, Puri L, Wood D. Bicompartamental knee arthroplasty: a bone-sparing, ligament-sparing, and minimally invasive alternative for active patients. *Orthopedics*. 2007 Aug;30(8 Suppl):70-3.
74. Romanowski MR, Repicci JA. Minimally invasive unicondylar arthroplasty: eight-year follow-up. *J Knee Surg*. 2002 Winter;15(1):17-22.
75. Satku K. Unicompartmental knee arthroplasty: is it a step in the right direction?—surgical options for osteoarthritis of the knee. *Singapore Med J*. 2003;44(11):554-6.
76. Schroer WC, Diesfeld PJ, LeMarr A, Reedy ME. Applicability of the mini-subvastus total knee arthroplasty technique: an analysis of 725 cases with mean 2-year follow-up. *J Surg Orthop Adv*. 2007 Fall;16(3):131-7.
77. Schroer WC, Diesfeld PJ, Reedy ME, LeMarr AR. Mini-subvastus approach for total knee arthroplasty. *J Arthroplasty*. 2008 Jan;23(1):19-25. Epub 2007 Sep 24.

78. Schroer WC, Diesfeld PJ, Reedy ME, Lemarr AR. Isokinetic Strength Testing of Minimally Invasive Total Knee Arthroplasty Recovery. *J Arthroplasty*. 2008 Dec 4.
79. Scott RD. UniSpacer: insufficient data to support its widespread use. *Clin Orthop*. 2003 Nov;(416):164-6.
80. Scuderi GR, Tenholder M, Capeci C. Surgical approaches in mini-incision total knee arthroplasty. *Clin Orthop Relat Res*. 2004 Nov;(428):61-7.
81. Scuderi GR, Tria AJ. Minimal incision total knee arthroplasty. *Techniques in Knee Surgery*. 2004 Jun;3(2):97-104.
82. Seon JK, Song EK. Navigation-assisted less invasive total knee arthroplasty compared with conventional total knee arthroplasty: a randomized prospective trial. *J Arthroplasty*. 2006 Sep;21(6):777-82.
83. Shankar NS. Minimally invasive technique in total knee arthroplasty - History, tips, tricks and pitfalls. *Injury*. 2006 Dec;37 Suppl 5:S25-30.
84. Sisto DJ, Mitchell IL. UniSpacer arthroplasty of the knee. *J Bone Joint Surg Am*. 2005 Aug;87(8):1706-11.
85. Sisto DJ; Sarin VK. Custom patellofemoral arthroplasty of the knee. *J Bone Joint Surg Am*. 2006 Jul;88(7):1475-80.
86. Sisto DJ, Sarin VK. Custom patellofemoral arthroplasty of the knee. Surgical technique. *J Bone Joint Surg Am*. 2007 Sep;89 Suppl 2 Pt.2:214-25.
87. Smith AM, Peckett WR, Butler-Manuel PA, Venu KM, d'Arcy JC. Treatment of patello-femoral arthritis using the Lubinus patello-femoral arthroplasty: a retrospective review. *Knee*. 2002 Feb;9(1):27-30.
88. Tashiro Y, Miura H, Matsuda S, Okazaki K, Iwamoto Y. Minimally invasive versus standard approach in total knee arthroplasty. *Clin Orthop Relat Res*. 2007 Oct;463:144-50.
89. Tauro B, Ackroyd CE, Newman JH, Shah NA. The Lubinus patellofemoral arthroplasty. A five- to ten-year prospective study. *J Bone Joint Surg Br*. 2001 Jul;83(5):696-701.
90. Tice JA. Knee joint spacer (UniSpacer) system for osteoarthritis of the knee. *Technology Assessment*. San Francisco, CA: California Technology Assessment Forum. Published February 12, 2003. Accessed March 10, 2009. Available at URL address: <http://www.ctaf.org/content/general/detail/552>
91. Tria AJ Jr, Coon TM. Minimal incision total knee arthroplasty: early experience. *Clin Orthop Relat Res*. 2003 Nov;(416):85-90.
92. Tria AJ. Minimally invasive total knee arthroplasty: the importance of instrumentation. *Orthop Clin North Am*. 2004 Apr;35(2):227-34.
93. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. 510(k) summary: Sulzer Orthopedics Unicondylar Interpositional Spacer. Accessed March 10, 2009. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=2646>
94. U.S. Food and Drug Administration (FDA). Minimally invasive solutions osteotomy guide instrument. 510(k) Premarket notification. Summary of safety and effectiveness. K033652. Accessed March 10, 2009. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=211&Panel=&ProductCode=&KNumber=&Model=&Applicant=&DeviceName=&Type=&ThirdPartyReviewed=off&ExpeditedReview=&Decision=&DecisionDateFrom=&DecisionDateTo=&IVDProducts=off&PAGENUM=10&SortColumn=Applicant%20DESC
95. Vail TP. Minimally invasive knee arthroplasty. *Clin Orthop Relat Res*. 2004 Nov;(428):51-2.

96. van Jonbergen HP, Werkman DM, Kampen A. Conversion of patellofemoral arthroplasty to total knee arthroplasty. Acta Orthop. 2009 Feb;80(1):62-6.
97. Whiteside LA. Mini incision: occasionally desirable, rarely necessary: in the affirmative. J Arthroplasty. 2006 Jun;21(4 Suppl 1):16-8.
98. Yang KY, Wang MC, Yeo SJ, Lo NN. Minimally invasive unicondylar versus total condylar knee arthroplasty—early results of a matched-pair comparison. Singapore Med J. 2003 Nov;44(11):559-62.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
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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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA’s subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.