

# Cigna Medical Coverage Policy



**Subject**    **Knee**  
              **Arthroplasty/Replacement**

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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
- customized knee replacement, including all of the following:
  - imaging studies (e.g., CT scans, MRI) associated with the customization
  - patient-specific template components and/or patient-specific instrumentation ( i.e., designed from patient imaging data)
  - customized knee prosthesis
  - gender specific prosthesis
- minimally invasive approaches to knee arthroplasty
- unicondylar interpositional spacer (e.g., UniSpacer®)
- focal resurfacing of a single knee joint defect (e.g., HemiCAP™, UniCAP™)

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## 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.

Knee joint failure often results from advanced, end stage joint 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 and press fit into place.

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, improved function and improved 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. However, in some cases failure occurs 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. There is no consensus regarding factors such as age and obesity affecting clinical outcomes (Palumbo, Scott, 2014). 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 (Sun and Jia, 2012; 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 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 occurs infrequently. Surgical treatment for isolated patellofemoral arthritis has been proposed for individuals 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 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 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.

The reported short- and mid-term results for patellofemoral arthroplasty vary across studies but in general are good and support improvement in pain, function and mobility. Although limited there is some recent data supporting long-term safety and efficacy (van Jonbergen, et al., 2010). Some patient populations overlap among studies and most are in the form of retrospective and prospective case series (Meding, et al., 2007; Ackroyd, et al., 2007; Sisto and Sarin, 2006; Ackroyd and Chir, 2005; Leadbetter, et al., 2005). Randomized controlled trials are limited. Average follow-up periods range from 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 studies. Improved survivorship has been reported with more recent implant designs (Odumanya, et al., 2010; van Jonbergen, et al., 2010).

Revision rates also vary across studies. 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). In a published review of the literature Delanois et al. (2008) 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. Authors suggest clinical results are dependent on prosthetic design, patient selection and technical proficiency.

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.

The use of custom-designed patellofemoral prosthetic devices versus off-the-shelf designs have been utilized with the goal of improving clinical outcomes, however published data evaluating these methods are lacking. Patellofemoral arthroplasty has been 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**

Bicompartmental knee replacement has been proposed for some patients with disease limited to the medial and patellofemoral compartments. With 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).

**Literature review:** Evidence evaluating bicompartmental or bi-unicompartmental knee replacement is limited to retrospective and prospective case series (Kamath, et al., 2014; Palumbo, et al., 2011; Heyse, et al., 2010; Parratte, et al., 2010; Rolston, et al., 2007; Confalonieri and Manzotti, 2006) with few prospective comparative trials (Chung, et al., 2013; Shah, et al., 2013; Morrison, et al., 2011, Confalonieri, et al., 2008). A majority of these studies involve use of different implants, involve small patient populations, and evaluate short- to mid-term outcomes using various assessment tools making comparisons across trials difficult. Outcomes such as durability/survival of the device, improvements in pain and function, and rates of revision, are mixed.

The results of one meta-analysis (Callahan, et al., 1995) evaluating unicompartmental and bicompartmental knee replacement were inconclusive. The authors reviewed 46 studies evaluating UKR involving 2391 patients and a mean follow-up of 4.6 years. For the bicompartmental 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 bicompartmental knee replacement appeared worse compared to the UKR, although they noted that patients who underwent the bicompartmental approach had poorer baseline knee function. Consequently, no reliable conclusions regarding efficacy could be made.

Consistent with earlier published clinical trials evaluating bicompartmental knee arthroplasty, the outcomes of more recent comparative clinical trials remain mixed. Chung et al. (2013) compared knee muscle strength and physical performance in a prospective trial involving subjects who underwent either bicompartmental or total knee arthroplasty (n=24). At six and 12 month follow-up there was no significant differences noted in muscle strength, position sense or physical performance compared to the total knee arthroplasty group. **Level 3** Shah et al. (2013) compared clinical and functional outcomes of bicompartmental (n=16) and total knee arthroplasty (n=20) at six, 12 and 24 months following surgery. Knee Society Scores (KSS), WOMAC pain and Knee Injury and Osteoarthritis Scores (KOOS) were statistically improved in both groups compared to preoperative values. Better knee range of motion was evident in the bicompartmental group compared to the TKA group at six, 12 and 24 months follow-up; however the results were not statistically significant.

Supporting evidence in the published scientific literature is limited and does not allow strong conclusions regarding improved patient outcomes with either a bi-unicompartmental or bicompartmental 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.

### **Emerging Technologies**

Emerging technologies aimed at improving clinical outcomes associated with TKR include technologies such as minimally invasive surgical approaches 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]), patient-specific template components and/or patient-specific instrumentation (designed from

patient imaging data), associated magnetic resonance or computerized tomography scans, and devices such as gender-specific total knee prostheses (e.g., Gender Solutions™ High Flex Knee [Zimmer Inc., Warsaw, IN]) are being investigated. Additionally, knee resurfacing of a focal knee joint surface has gained interest as an alternative to TKR.

**Patient-Specific Templates/Instrumentation:** During knee replacement surgery a portion of the knee is resected using instrumentation guided by templates or cutting devices. Prosthetic devices are then used to replace the joint components. Patient-specific templates and/or instrumentation devices are being investigated as an alternative to standard equipment for both total and partial knee replacement to aid in more properly designing and aligning the implants. These devices are used to assist with marking an area before cutting the bone and then positioning of the knee components. With this technique a few weeks prior to surgery preoperative images are obtained using computed tomography or magnetic resonance imaging for the development of a knee model which is then used to develop specially sized prosthetic components based on an individual's anatomy.

**U.S. Food and Drug Administration (FDA):** Various instrumentation systems and software systems for developing patient specific templates/instrumentation are currently available. These devices are regulated by the U.S. Food and Drug Administration (FDA) through the 510(k) marketing process. Devices that have received FDA approval include but are not limited to the following: TruMatch Solutions (DePuy Orthopaedics, Inc.), Visionaire Patient matched Cutting Blocks (Smith and Nephew, Inc) and Stryker Patient Specific Cutting Guide (Stryker Corporation).

**Literature Review:** Evidence in the peer reviewed published literature is conflicting, some studies support there is improvement in outcomes such as better mechanical alignment with the use of these devices ( Ng, et al., 2012; Noble, et al., 2012; Spencer, et al., 2009). However, authors have also reported there is minimal to no relevant difference in alignment (Abdel, et al., 2014; Kerens, et al., 2014). Overall effects for improvement of net health outcomes have yet to be determined. Published data supporting improved functional outcomes is lacking. In 2011 ECRI published an emerging technology report and concluded that there was insufficient evidence to evaluate clinical efficacy of these devices compared to conventional instrumentation (ECRI, 2011). Due to insufficient published scientific evidence available at this time the overall benefit of patient-specific templates/instrumentation systems compared to conventional instrumentation has yet to be determined.

**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, 2007). 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).

**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 (Lai, et al., 2014; Essving, et al., 2012; Kim, et al., 2011; 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. The results of an evidence technology report published by ECRI (2011) concluded that MIS TKR resulted in a significantly greater improvement of KSS total scores at six month follow-up compared to conventional TKR and there were no differences in adverse event rates. The published data was insufficient to support conclusions for outcomes including but not limited to pain, function, activities of daily living, Oxford knee score, ability to walk independently, patient satisfaction and knee strength. ECRI noted additional studies are needed to support long term outcomes and that MIS TKR outcomes are at least as good as those obtained with conventional TKR.

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). Ghandi et al. (2011) reported the results of meta-analysis of RCTs to compare complication rates between MIS TKR and standard TKR. A total of nine RCTs were included in the review. The authors noted a statistically significant increase in complication rates for the MIS group when compared to standard TKR and that MIS TKR failed to demonstrate any clinical benefit. 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).

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 (Lai, et al., 2014; Tasker, et al., 2014; Kim, et al., 2011; Varela-Egocheaga, et al., 2010; Wulker, et al., 2010; Pan, et al., 2010; Hernandez-Vaquero, et al., 2010). A majority are limited by small sample populations and short-term outcomes. Lai et al. (2014) reported the results of a prospective RCT comparing clinical and radiographic results of primary TKR (n=33) and mini-subvastus approach (n=35). At an average follow-up of 28

months following surgery there were no significant differences in Knee Society function score, Oxford knee score, and range of motion. In addition the authors noted reduced access and visibility resulted in more technical errors and increased tourniquet time. Tasker et al. (2014) reported the results of a prospective RCT comparing MIS TKR (n=48) with TKR (n=54). The primary measured outcome was length of stay; secondary outcomes included WOMAC, KSS, Oxford scores, and knee ROM. Follow-up occurred at three, 12, and 24 months. The MIS group had a shorter length of stay and fewer surgical complications, there was no significant difference in operative time or alignment, and postoperative functional improvements were not statistically different between groups.

Kim et al., (2011) evaluated muscle strength in patients who underwent TKR using either a MIS approach (N=23) or a conventional approach TKR (N=22). The results of this randomized, controlled, double blind trial support that MIS resulted in better outcomes in regard to maintaining quadriceps extensor strength compared to the conventional approach. At 12 months follow-up, the MIS group had slightly better clinical scores compared to those treated with conventional surgery. Another 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.

Li et al. (2014) reported the results of a meta-analysis comparing clinical and radiological outcomes of MIS TKR with conventional TKR. Thirty studies were reviewed in total (28 RCTs, 2 prospective trials), including 2,536 TKR (1,259 MIS, 1,277 conventional). The primary clinical outcome was KSS; secondary outcome included WOMAC scores, Oxford knee scores, HSS score, VAS, ROM, and technical operative outcomes. Follow-up ranged from two to 96 months. The authors reported operative and tourniquet times were longer for the MIS group, however the MIS group demonstrated better total and objective KSS, less blood loss, VAS, range of motion and straight leg raising, resulting in a faster recovery compared to conventional TKR. There were no significant differences reported between the two groups in leg alignment (valgus), femoral, anterior/lateral angle, tibia anterior/lateral angle or patellae component angle. There were no differences in other clinical or radiological outcomes. The meta-analysis supports improvement in some short-term outcomes such as total and objective KSS; however it is limited by lack of medium and long term outcomes which are required to determine a net health benefit.

Costa et al. (2012) reported the results of a systematic review of minimally invasive approaches in knee arthroplasty. A total of 23 studies were included in the review, 13 level 1 prospective randomized trials and 10 level II studies comparing a total of 1141 MIS TKA with 745 TKA using standard approaches. The authors reviewed early perioperative outcomes, clinical outcomes using various knee scoring systems, incidence and type of complications, revision rates and radiographic outcomes. A significant difference was observed for recovery of quadriceps muscle function, favoring the minimally invasive approaches. However, there were no significant differences reported for any other outcome.

MIS UKR has also been investigated and some authors have reported encouraging results (O'Donnell, 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%.

**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.

**Focal Joint Resurfacing:** Focal resurfacing of a knee joint defect is a surgical procedure in which a limited amount of bone is removed from the surface of the joint and then replaced with a metal or metal/plastic implant. It has been proposed as an alternative to UKR or TKR involving less removal of the patient's bone and theoretically allowing more normal joint function. Candidates for resurfacing are usually younger in age, physically active, and have focal articular defects (i.e., early stage OA changes that are isolated).

**U.S. Food and Drug Administration (FDA):** Two FDA approved knee resurfacing prosthesis include the HemiCAP™ Femoral Condyle System (Arthrosurface, Inc., Franklin, MA) and the UniCAP™ Unicompartmental Knee Resurfacing Implant (Arthrosurface, Inc., Franklin, MA). These devices are approved through the FDA 510(k) approval process as Class II devices and are intended to be used with bone cement.

**Literature Review:** Evidence in the peer-reviewed published scientific literature evaluating safety and efficacy of focal knee joint resurfacing using these or other similar devices is limited. Becher et al. (2011) published the results of a case series involving 21 patients who received a HemiCap device with average follow-up of 5.3 years. Boller et al. reported the results of a case series involving 19 subjects treated with a HemiCap device with an average follow-up of 34 months. Although there was improvement in pain and function scores, the studies were limited by small populations, lack of a control group and short to mid-term outcomes. Published data regarding the safety, efficacy and improved health outcomes with the use of this technology as an alternative to TKR or UKR is insufficient and precludes the ability to draw conclusions as this time.

**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:** In 2003 the California Technology Assessment Forum (CTAF) (Tice, 2003) reported that no published studies were available to assess the safety and efficacy of the UniSpacer device. CTAF noted that surgical placement of knee joint spacer devices requires evaluations in controlled trials to determine safety and efficacy before widespread adoption can be recommended. At present, evidence in the published scientific literature evaluating the UniSpacer and other similar devices remains limited (Catier, et al., 2010; Bailie, et al., 2008; Sisto and Mitchell, 2005; Hallock and Fell, 2003). A majority of the studies involve small sample populations and evaluate short-term clinical outcomes. Long-term clinical outcomes including randomized controlled trials are lacking. In addition, 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. Some authors reported unsatisfactory results including persistent pain and need for revision with either implant replacement or total knee arthroplasty (Bailie, et al., 2008; Sisto and Mitchell, 2005; Hallock and Fell, 2003). As a result of high revision rates and uncertain clinical utility some authors noted they no longer recommend use of the device (Catier, et al., 2010; Sisto and Mitchell, 2005).

**Use Outside of the US:** Countries outside the United States, including but not limited to Canada and Europe classify knee implant devices similar to the US FDA process and assign classifications of the device based on level of risk. Additionally some countries have established total joint arthroplasty registries to track various devices and associated outcomes.

Regarding specific recommendation/guidelines, the National Institute for Health and Care Excellence (NICE) issued a procedural guidance regarding mini-incision surgery for total knee replacement (March, 2010). The Institute concluded that current evidence on the safety and efficacy of mini-incision surgery for total knee replacement is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. In addition, NICE reported the current evidence on the safety and efficacy of individually magnetic resonance imaging (MRI)-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee is inadequate in quantity and quality; the procedure should only be used in the context of a clinical trial (NICE, 2009).

## 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, bi-unicompartmental knee replacement, or focal knee joint resurfacing. 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 unicompartmental 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.

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## Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible

for reimbursement

### **Total Knee Replacement**

**Covered when medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
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)

### **Revision Total Knee Replacement**

**Covered when medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
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

### **Unicompartmental Knee Replacement**

**Covered when medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
27438	Arthroplasty, patella; with prosthesis
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment

**Experimental, investigational, unproven, and not covered when used to report focal resurfacing of a single knee joint defect and the associated implant:**

<b>CPT* Codes</b>	<b>Description</b>
27438	Arthroplasty, patella; with prosthesis
27440	Arthroplasty, knee, tibial plateau
27442	Arthroplasty, femoral condyles or tibial plateau(s), knee;

<b>HCPCS</b> <b>Codes</b>	<b>Description</b>
C1776	Joint device (implantable)
L8699	Prosthetic implant, not otherwise specified

**Experimental, investigational, unproven and not covered when used to report a unicompartmental interpositional spacer (e.g., UniSpacer), minimally invasive knee arthroplasty, or bicompartamental/bi-unicompartmental arthroplasty or patient-specific templates/instrumentation:**

<b>CPT* Codes</b>	<b>Description</b>
27599	Unlisted procedure, femur or knee

**\*Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.**

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