

Health Technology Clinical Committee

Findings and Coverage Decision

Topic: Total Knee Arthroplasty

Meeting Date: October 22nd, 2010

Final Adoption: December 10th, 2010

Number and Coverage Topic

20101022A – Total Knee Arthroplasty

HTCC Coverage Determination

Computer navigated and unicompartmental knee arthroplasty is a **covered benefit** for treatment of osteoarthritis and rheumatoid arthritis of the knee.

Multi-compartmental arthroplasty is **not a covered benefit**.

HTCC Reimbursement Determination

❖ **Limitations of Coverage**

For treatment of end stage osteoarthritis and rheumatoid arthritis of the knee:

- Total Knee Arthroplasty with Computer Navigation is a covered benefit.
- For individuals with uni-compartmental disease, uni-compartmental partial Knee Arthroplasty is a covered benefit.

❖ **Non-Covered Indicators**

- Multi-compartmental partial knee arthroplasty, (including bi-compartmental and bi-uni compartmental) is not a covered benefit.

❖ **Agency Contact Information**

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

Health Technology Background

The Total Knee Arthroplasty topic was selected and published in December 2009 to undergo an evidence review process. The evidence based technology assessment report indicates that conventional total knee arthroplasty (CONV-TKA) is an effective treatment for end stage knee arthritis. Over time, technologies to improve CONV-TKA have been introduced. Whether these technologies improve CONV-TKA and are efficacious or cost-effective is uncertain. Two of these technologies, computer-navigated total knee arthroplasty (CN-TKA) and partial knee arthroplasty are the subject of this HTA. *Indications for CN-TKA – similar to CONV-TKA:* Moderate to severe arthritic knee pain that has not adequately responded to a prolonged course of nonsurgical treatment, **and** radiological evidence of joint damage, **and** lower quality of life due to clinically significant limitations in function. *Indications for partial knee arthroplasty:* Similar to TKA except that the arthritis is limited to one compartment (medial or lateral for unicompartmental) or to two compartments (medial or lateral and patellofemoral for bicompartamental). Partial knee arthroplasty traditionally reserved for relatively inactive elderly patients, but is being used with increasing frequency in younger, more active patients.

Key points to consider: CN-TKA reduces the risk of unsatisfactory alignment of the mechanical axis (> 3°) compared with CONV-TKA. Despite this, there is no evidence in the short term (<3 years) that CN-TKA results in better patient reported, clinical or QoL outcomes. Only short term revision rates are available from small studies and they are inconsistent. There appears to be fewer emboli following CN-TKA than CONV-TKA as measured by the Mayo Clinic Score. This is attributed in part to the absence of use of the femoral IM guide in CONV-TKA. However, its clinical importance is not known. VTE events are similar between CN-TKA and CONV-TKA as are wound and other complications. Postoperative transient confusion occurred slightly less frequently one RCT and markedly less frequently in a second among those receiving CN-TKA.

UKA and bicompartamental KA: Pain and function appear to be similar comparing UKA and TKA in patients with unicompartmental disease. ROM is consistently higher in patients receiving UKA. Revision rates tend to be slightly higher in the UKA vs. TKA group in most studies up to 10 years of follow-up. Likewise, prosthesis survival slightly favors TKA at 10-14 year follow-up. The safety profile with respect to mortality, VTE, wound complications and other complications is similar between UKA and TKA. Bicompartamental knee arthroplasty in two large registry studies had similar survival 2-4 years following surgery.

Cost-Effectiveness: There is insufficient revision data to conclude whether CN-TKA is cost effective. Modeling suggest that the 10 year revision rate would need to be reduced between 33%-50% of CONV-TKA for potential cost savings. There is some evidence that UKA and TKA have similar cost and QALY outcome profiles in older patients (mean age of 70 years), but this evidence depends on assumption that need verification with longer studies.

In August 2010, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed Total Knee Arthroplasty report is 173 pages, and identified a relatively large amount of literature.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on October 22nd, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at <http://www.hta.hca.wa.gov> under the committee section.

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

The committee concludes that the best available evidence on Total Knee Arthroplasty (TKA) has been collected and summarized. The evidence is presented below:

- The evidence based technology assessment report indicates that in 2005, over 555,000 TKA procedures were performed in the United States, a 69% increase compared with 1997. The high prevalence of knee arthritis in the population is reflected in the high cost of treatment, which has been estimated at \$6.3 billion per year.
- The evidence based technology assessment report summarized the evidence on CONV-TKA for end stage knee arthritis as effective in improving short and long term outcomes and quality of life. However, questions remain about when the procedure is most appropriate and for whom, and whether certain types of knee replacement procedures produce better results.
- The evidence based technology assessment report summarized TKA as a procedure in which articular surfaces of the medial and lateral compartments are replaced. The patellofemoral articular surface may or may not be replaced in TKA. The conventional method of achieving limb alignment in TKA includes use of anatomic landmarks and special jigs provided with the knee prosthesis. Conventional TKA (CONV-TKA) is the current standard for knee arthroplasty. Computer-navigated (CN-TKA), a more expensive procedure, provides an alternative method of achieving correct limb alignment.
- Less invasive procedures that seek to treat only the diseased compartments of the knee have been recently developed and are now being advocated for younger more active patients. These procedures are referred to as partial knee arthroplasty and include the unicompartmental knee arthroplasty (UKA) or bicompartamental knee arthroplasty (BKA).
- Evidence included in the technology assessment review was obtained through systematic searches of the medical literature for relevant systematic reviews including meta-analyses, other diagnostic studies, randomized controlled trials and economic studies. Selected national guidelines and previous technology assessment were also summarized in the technology assessment report.
- The evidence based technology assessment report identified six expert treatment guidelines and there is no National Coverage decision on TKA and various surgical techniques.
- The committee also reviewed information provided by the state agencies, and public members; and heard comments from the evidence reviewer, clinical expert, HTA program, the public and agency medical directors.

2. Is the technology safe?

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

- Overall safety outcomes for TKA: The evidence based technology assessment report reported several key outcomes related to safety of TKA, including: deep vein thrombosis (DVT), pulmonary embolism (PE), ischemic events, tourniquet time, infections, wound and other complications. In general, the evidence was low but did not suggest significant differences in safety outcomes between surgical techniques for TKA.
- CONV-TKA and CN-TKA: The evidence based technology assessment report concluded that high evidence was found to suggest that CN-TKA is as safe as CONV-TKA.

- Several RCTs and cohort studies reported no significant differences between CN-TKA and CONV-TKA with respect to thromboembolic events, infection or all other complications other than ischemic events.
- The evidence based technology assessment report concluded that one RCT reported no significant differences in acute myocardial infarction and one reported no difference in transient ischemia following CN-TKA vs. CONV-TKA.
- CONV-TKA and UKA or bi-UKA: The evidence based technology assessment report concluded very low evidence exists that complications were infrequent, and the risk of complications was similar between UKA and TKA in one RCT and nine cohort studies. One small cohort study reported 2 cases (9%) of intraoperative fracture of the tibial spine in the bi-UKA group. No other complications reported.
- Simultaneous or staged bilateral TKA: The evidence based technology assessment report concluded low evidence from four cohort studies which reported 30 day mortality rates following either staged or simultaneous TKA. Three of the four cohort studies reported significantly higher rates in the simultaneous group.
 - The evidence based technology assessment report concluded from nine cohort studies no significant differences in thromboembolic events, wound complications, or other complications between simultaneous and staged bilateral TKA.

3. Is the technology effective?

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

- Overall identified efficacy outcomes for TKA: The evidence based technology assessment report reported several key outcomes related to efficacy of TKA, including outcomes of: revision and removal rates; pain relief; functional improvement; quality of life; range of motion; prosthesis survival and radiographic outcomes.
- *Knee Pain, Function and Quality of Life – CN-TKA vs. CONV-TKA*: The evidence based technology assessment report concluded that several high evidence randomized controlled trials reported similar results in pain, function and quality of life outcomes when comparing patients receiving either CN-TKA or CONV-TKA at various follow-up times ranging from 3 months to 2 years. The data are similar with respect to nonrandomized cohort studies with 1 to 3 year follow-up. No comparative data are available for these outcomes past 2 to 3 years.
- *Revision – CN-TKA vs. CONV-TKA*: The evidence based technology assessment report concluded low evidence from two RCTs and two cohort studies which reported similar, low rates between CN-TKA and CONV-TKA groups of less than 2%. A third RCT reported half as many revisions following CN-TKA (3.7% vs. 8.0%) after 3 years. Due to the small sample sizes, short follow up, and inconsistent rate of revision among the RCTs renders low evidence concerning the relative short term revision rates between surgeries. Conclusions on whether CN-TKA affects long term revision rates are premature.
- *Alignment– CN-TKA vs. CONV-TKA* : The evidence based technology assessment report concluded that high evidence from 2 meta-analyses of several RCTs and cohort studies demonstrate that the risk of unsatisfactory alignment by more than 3° is significantly less using CN-TKA compared with CONV-TKA.
- *UKA vs. TKA – Knee Pain and Function*: Moderate evidence exists that knee pain and function were comparable between UKA and TKA in one RCT and 14 cohort studies over a variety of follow-up times ranging from 3 months to 15 years. Range of motion was consistently higher in the UKA group in the studies comparing mean motion and the proportion of patients achieving $\geq 120^\circ$ of flexion at a variety of follow-up times.
- *UKA vs. TKA – Revision, prosthesis survival*: Low evidence exists that revision rates were comparable between UKA and TKA in one RCT at 5 and 15 year follow-up. In 9 cohort studies

that rates of revision were slightly higher in the UKA compared with TKA group in 8, mean follow up between 2 and 10 years. Survival of the arthroplasty in two large studies at 10 and 14-15 years slightly favored TKA.

- Bi-UKA vs. TKA – Knee Pain, Function and Revision: Only one small retrospective cohort very low evidence study compared bi-UKA with TKA. No difference was found in functional scores at a minimum of 4 year follow up. No revisions were recorded in either group.
- Bicompartamental knee arthroplasty vs. TKA – Revision: Two large registry studies comparing revision between bicompartamental knee arthroplasty and tricompartmental TKA found similar revision rates and 2 to 4 year implant survival.

4. Special Populations?

- CONV-TKA : the evidence based technology assessment reported concluded ~
 - *Age, sex, obesity, comorbidity*: very low evidence from one HTA and studies published after the HTA reported inconsistent results as to whether age, sex, obesity or comorbidity significantly affected outcomes.
 - *Type of arthritis*: moderate evidence from one HTA reported greater improvement in baseline functional scores among rheumatoid arthritis (RA) patient compared with Osteoarthritis (OA) patients. One prospective study published after the HTA indicated no difference in function/quality of life outcomes based on type of arthritis type.
 - *Hospital, surgeon volume and other characteristics*: very low evidence from one systematic review of several studies reported mixed results with respect to morbidity, mortality and length of stay. One study reported on possible associations between preoperative pain levels, length of hospital stay, waiting time, year of follow-up, education, SF-36 mental health scores and ethnicity and outcomes.
- CN-TKA: the evidence based technology assessment reported concluded ~
 - *Obesity*: one very low evidence retrospective study reported that morbidly obese patients experienced a significantly greater mean total blood loss, mean hemoglobin loss, and superficial infection rate compared with those of normal weight.
- UKA: the evidence based technology assessment reported concluded ~
 - *Age*: five of six registry studies reported a statistically significant higher revision rate among patients < 65 years of age versus those > 65 years of age. The higher quality studies consistently found a greater risk among patients < 65 years of age; therefore, there is high evidence to suggest that younger patients are at greater risk of failure after UKA than older patients.
 - *Obesity*: among three retrospective cohort studies evaluating obesity as a risk factor, one found higher rates among obese, one found lower rates among obese, and the 3rd found no statistically significant difference.
 - *Sex*: five of seven high evidence published studies found no association between sex and UKA failure. Among the two that found an association, both were LoE III retrospective cohort studies. One reported a higher revision rate among males, the other a higher revision rate among females. The higher quality studies consistently found no association between sex and revision.
 - *Multi-compartmental*: One LoE II registry study reported higher rates of revision among patients with RA compared to those with OA.
- *Provider Facility*: Two low evidence LoE II studies found no statistically significant difference in revision rates among caseloads ≤ 10 or > 10 UKAs per year; and one study did not find an association between different surgeons or different hospitals on revision rates.

5. Is the technology cost-effective?

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

- CN-TKA: the evidence based technology report concluded that there is insufficient data to make strong conclusion about the long-term cost effectiveness of CN-TKA.
 - Modeling suggests that CN-TKA is potentially cost effective intervention compared with CONV-TKA if the 10-year revision rate is reduced by between 33 to 50%; this assumption is not supported by current high or moderate quality clinical evidence.
- UKA vs. TKA: the evidence based technology report concluded some evidence exists to indicate that UKA and TKA have similar cost and quality-adjusted outcome profiles from a health care perspective. Lack of data precludes assessment of the cost effectiveness of UKA in people under the age of 65.
- Washington state agency utilization and cost information indicated that the UMP, L&I and DSHS have paid a total of \$80.6 million dollars on TKA related costs in the last 4 years.
 - L&I additional payment for Computer navigation CPT Code is \$234.00

6. Medicare Decision and Expert Treatment Guidelines

Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report.

- Centers for Medicare and Medicaid Services (CMS) – no NCD policy.
- Guidelines – the evidence based technology assessment report identified six guidelines though a search of the *National Guideline Clearinghouse* identified no guidelines specific to unicompartmental, bicompartamental, bi-unicompartmental, total knee arthroplasty, or computer-assisted knee arthroplasty for the treatment of end-stage knee arthritis.
 - *National Institute for Health and Clinical Excellence (NICE)* -- No specific guidelines were found that addressed unicompartmental, bicompartamental, bi-unicompartmental, total knee arthroplasty, or computer-assisted knee arthroplasty for the treatment of end-stage knee arthritis from the National Institute for Health and Clinical Excellence (NICE), which provides guidance on health technologies and clinical practice for the National Health Service in England and Wales.
 - *NIH Consensus Statement on Total Knee Replacement* -- Technical factors in performing surgery may influence both the short- and long-term success rates. Proper alignment of the prosthesis appears to be critical in minimizing long-term wear, risk of osteolysis, and loosening of the prosthesis. Computer navigation may eventually reduce the risk of substantial malalignment and improve soft tissue balance and patellar tracking. However, the technology is expensive, increasing operating room time, and the benefits remain unclear.
 - *Ontario Health Technology Advisory Committee (OHTAC)* -- Concluded that computer-assisted arthroplasty using navigation systems is considered to be in the investigational stage. Current studies have only assessed short-term outcomes, and long-term effectiveness (need for revision, implant longevity, pain, and functional performance) has not been demonstrated.
 - *Osteoarthritis Research Society International (OARSI)* -- OARSI published 23 treatment guidelines for the management of hip and knee osteoarthritis identified from a literature search, including six opinion-based, five evidence-based and 12 based on both expert opinion and research evidence.
 - Relevant guidelines for this report are: unicompartmental knee replacement is effective in patients with knee osteoarthritis restricted to a single compartment.

- For the young and physically active patient with significant symptoms from unicompartmental knee osteoarthritis, high tibial osteotomy may offer an alternative intervention that delays the need for joint replacement some 10 years.
- *American Academy of Orthopedic Surgeons (AAOS)* -- No specific clinical guidelines for knee arthroplasty were found; however, recommendations are due to be published in September 2010.

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on Total Knee Arthroplasty demonstrates that there is sufficient evidence to cover computer navigated and unicompartmental knee arthroplasty for treatment of osteoarthritis and rheumatoid arthritis of the knee. The committee agreed that there is insufficient evidence on multi-compartmental arthroplasty; therefore, the committee unanimously agreed to not cover. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted 5 to 3 to cover computer navigated TKA. Based on these findings, the committee voted 6 to 2 to cover unicompartmental TKA. Based on these findings, the committee voted 8 to 0 to not cover multi-compartmental TKA.

For treatment of end stage osteoarthritis and rheumatoid arthritis of the knee:

- Total Knee Arthroplasty with Computer Navigation is a covered benefit.
- For individuals with uni-compartmental disease, uni-compartmental partial Knee Arthroplasty is a covered benefit.
- Multi-compartmental partial knee arthroplasty, (including bi-compartmental and bi-uni compartmental) is not a covered benefit.

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.