Computer-Assisted Navigation for Orthopedic Procedure

I. Description

Computer-assisted navigation (CAN) in orthopedic procedures describes the use of computer-enabled tracking systems to facilitate alignment in a variety of surgical procedures, including fixation of fractures, ligament reconstruction, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

For individuals who are undergoing orthopedic surgery for trauma or fracture, ligament reconstruction, hip arthroplasty and periacetabular osteotomy, or total knee arthroplasty who receive CAN, the evidence includes randomized controlled trials (RCTs) and nonrandomized comparative studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Overall, the literature supports a decrease in variability of alignment with CAN, particularly with respect to the number of outliers. Although some observational data have suggested that malalignment may increase the probability of early failure, recent RCTs with short- to mid-term follow-up have not shown improved clinical outcomes with CAN. Given the low short-term revision rates associated with conventional procedures and the inadequate power of the available studies to detect changes in function using CAN, studies are needed that assess health outcomes using CAN in a larger number of subjects with longer follow-up to permit greater certainty on the impact of this technology. The evidence is insufficient to determine the effects of the procedure on health outcomes.

Background

The goal of computer-assisted navigation (CAN) is to increase surgical accuracy and reduce the chance of malposition of implants. For total knee arthroplasty (TKA), malalignment is commonly defined as a variation of greater than 3° from the targeted position. Proper implant alignment is believed to be an important factor for minimizing long-term wear, risk of osteolysis, and loosening of the prosthesis. In addition to reducing the risk of substantial malalignment, CAN may improve soft tissue balance and patellar tracking. CAN is also being investigated for operations with limited visibility such as placement of the acetabular cup in total hip arthroplasty (THA), resection of pelvic tumors, and minimally invasive orthopedic procedures. Other potential uses of CAN for surgical
procedures of the appendicular skeleton include screw placement for fixation of femoral neck fractures, high tibial osteotomy, and tunnel alignment during reconstruction of the anterior cruciate ligament.

CAN devices may be image-based or non-image-based. Image-based devices use preoperative computed tomography (CT) scans and operative fluoroscopy to direct implant positioning. Newer non-image-based devices use information obtained in the operating room, typically with infrared probes. For TKA, specific anatomic reference points are made by fixing signaling transducers with pins into the femur and tibia. Signal-emitting cameras (e.g., infrared) detect the reflected signals and transmit the data to a dedicated computer. During the surgical procedure, multiple surface points are taken from the distal femoral surfaces, tibial plateaus, and medial and lateral epicondyles. The femoral head center is typically calculated by kinematic methods that involve movement of the thigh through a series of circular arcs, with the computer producing a 3-dimensional (3D) model that includes the mechanical, transepicondylar, and tibial rotational axes. CAN systems direct the positioning of the cutting blocks and placement of the prosthetic implants based on the digitized surface points and model of the bones in space. The accuracy of each step of the operation (cutting block placement, saw cut accuracy, seating of the implants) can be verified, thereby allowing adjustments to be made during surgery.

Navigation involves 3 steps: data acquisition, registration, and tracking.

Data Acquisition
Data can be acquired in 3 different ways: fluoroscopically, guided by CT scan or magnetic resonance imaging (MRI) or guided by imageless systems. These data are then used for registration and tracking.

Registration
Registration refers to the ability of relating images (i.e., radiographs, CT scan, MRI or patients’ 3D anatomy) to the anatomical position in the surgical field. Registration techniques may require the placement of pins or “fiduciary markers” in the target bone. A surface-matching technique can also be used in which the shapes of the bone surface model generated from preoperative images are matched to surface data points collected during surgery.

Tracking
Tracking refers to the sensors and measurement devices that can provide feedback during surgery regarding the orientation and relative position of tools to bone anatomy. For example, optical or electromagnetic trackers can be attached to regular surgical tools, which can then provide real-time information of the position and orientation of the tools’ alignment with respect to the bony anatomy of interest.

The VERASENSE™ (OrthoSense™) is a single-use device that replaces the standard plastic tibial trial spacer used in TKA. The device contains microprocessor sensors that quantify load and contact position of the femur on the tibia after resections have been made. The wireless sensors send the data to a graphic user Interface that depicts the load. The device is intended to provide
quantitative data on the alignment of the implant and on soft tissue balancing in place of intraoperative “feel”.

iASSIST™ (Zimmer) is an accelerometer-based alignment system with the user interface built into disposable electronic pods that attach onto the femoral and tibial alignment and resection guides. For the tibia, the alignment guide is fixed between the tibial spines and a claw on the malleoli. The relationship between the electronic pod of the digitizer and the bone reference is registered by moving the limb into abduction, adduction, and neutral position. Once the information has been registered, the digitizer is removed and the registration data are transferred to the electronic pod on the cutting guide. The cutting guide can be adjusted for varus/valgus alignment and tibial slope. A similar process is used for the femur. The pods use wireless exchange of data and display the alignment information to the surgeon within the surgical field. A computer controller must also be present in the operating room.

**Regulatory Status**

Because CAN is a surgical information system in which the surgeon is only acting on the information that is provided by the navigation system, surgical navigation systems generally are subject only to 510(k) clearance from FDA. As such, FDA does not require data documenting the intermediate or final health outcomes associated with CAN. (In contrast, robotic procedures, in which the actual surgery is robotically performed, are subject to the more rigorous requirement of the premarket approval application process.)

A variety of surgical navigation procedures have received FDA clearance through the 510(k) process with broad labeled indications. The following is an example:

“The OEC FluoroTrak 9800 Plus provides the physician with fluoroscopic imaging during diagnostic, surgical and interventional procedures. The surgical navigation feature is intended as an aid to the surgeon for locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, long bone or vertebra visible on fluoroscopic images.”

Several navigation systems (e.g., PiGalileo™ Computer-Assisted Orthopedic Surgery System, PLUS Orthopedics; OrthoPilot® Navigation System, Braun; Navitrack® Navigation System, ORTHOsoft) have received FDA clearance specifically for TKA. FDA-cleared indications for the PiGalileo system are representative. This system “is intended to be used in computer-assisted orthopedic surgery to aid the surgeon with bone cuts and implant positioning during joint replacement. It provides information to the surgeon that is used to place surgical instruments during surgery using anatomical landmarks and other data specifically obtained intraoperatively (e.g., ligament tension, limb alignment). Examples of some surgical procedures include but are not limited to:

- Total knee replacement supporting both bone referencing and ligament balancing techniques
- Minimally invasive total knee replacement”
FDA product code: HAW.

In 2013, the VERASENSE™ Knee System from OrthoSensor™ and the iASSIST™ Knee from Zimmer received 510(k) clearance from the FDA.

II. Criteria/Guidelines

Computer-assisted surgery for orthopedic procedures of the pelvis and appendicular skeleton is not covered as it is not known to be effective in improving health outcomes.

III. Administrative Guidelines

The following CPT codes are not covered:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20985</td>
<td>Computer-assisted surgical navigational procedure for musculoskeletal procedures; image-less (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0054T</td>
<td>Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image guidance based on fluoroscopic images (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0055T</td>
<td>Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image guidance based on CT and MRI images. (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0396T</td>
<td>Intra-operative use of kinetic balance sensor for implant stability during knee replacement arthroplasty (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

IV. Scientific Background

This policy is updated periodically using the MEDLINE database. The most recent literature search was performed through November 7, 2016.

For many orthopedic surgical procedures, optimal alignment is considered an important aspect of long-term success. For example, misplaced tunnels in anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) reconstruction or malalignment of arthroplasty components are some of the leading causes of instability and reoperation. In total hip arthroplasty (THA), orientation of the acetabular component of the THA is considered critical, while for total knee arthroplasty (TKA), alignment of the femoral and tibial components and ligament balancing are considered important outcomes. Ideally, one would prefer controlled trials comparing the long-term outcomes, including stability and reoperation rates. Intermediate outcomes include the number of procedures that achieve a predetermined level of acceptable alignment.

Trauma or Fracture
Computer-assisted surgery has been described as an adjunct to pelvic, acetabular, or femoral fractures. For example, fixation of these fractures typically requires percutaneous placement of screws or guidewires. Conventional fluoroscopic guidance (i.e., C-arm fluoroscopy) provides imaging in only one plane. Therefore, the surgeon must position the implant in one plane and then get additional images in other planes in a trial and error fashion to ensure that the device has been properly placed. This process adds significant time in the operating room and radiation exposure. It is hoped the computer-assisted surgery would allow for minimally invasive fixation and provide more versatile screw trajectories with less radiation exposure. Therefore, computed-assisted surgery is considered an alternative to the existing image guidance using C-arm fluoroscopy.

Ideally, one would like controlled trials comparing operating room time, radiation exposure, and long-term outcomes of those whose surgery was conventionally guided using C-arm versus image-guided using computer-assisted surgery. While several in vitro and review studies had been published, a literature search at the time this policy was created identified only one clinical trial of computer-assisted surgery in trauma or fracture cases. Computer-assisted navigation (CAN) for internal fixation of femoral neck fractures has been described in a retrospective analysis consisting of 2 cohorts of consecutive patients (20 each, performed from 2001 to 2003 at 2 different campuses of a medical center) who underwent internal fixation with 3 screws for a femoral neck fracture. Three of 5 measurements of parallelism and neck coverage were significantly improved by CAN; these included a larger relative neck area held by the screws (32% vs. 23%) and less deviation on the lateral projection for both the shaft (1.7° vs. 5.2°) and the fracture (1.7° vs. 5.5°, all respectively) screw angles. Slight improvements in anteroposterior screw angles (1.3° vs. 2.1° and 1.3° vs. 2.4°, respectively) did not reach statistical significance. There were 2 reoperations in the CAN group and 6 in the conventional group. Complications (collapse, subtrochanteric fracture, head penetration, osteonecrosis) were lower in the CAN group (3 vs. 11, respectively).

Section Summary: Trauma or Fracture

There is limited literature on the use of CAN for trauma or fractures. Additional controlled studies that measure health outcomes are needed to evaluate this technology.

Anterior Cruciate Ligament or Posterior Cruciate Ligament Reconstruction

Cochrane review from 2011 and 2014 assessed the effects of CAN in comparison with conventional operating techniques for ACL or posterior cruciate ligament (PCL) reconstruction. Five randomized controlled trials (RCTs, 366 participants) on ACL reconstruction were included in the review; no studies involved PCL reconstruction. The quality of evidence ranged from moderate to very low. Pooled data showed no statistically or clinically relevant differences in self-reported health outcomes (International Knee Documentation Committee [IKDC] subjective scores and Lysholm scores) at 2 or more years of follow-up. No significant differences were found for secondary outcomes, including knee stability, range of motion, and tunnel placement. Overall, there was insufficient evidence to advise for or against the use of CAN. Four of the 5 trials included in the Cochrane review are described next.

One of the studies randomized 60 patients to either manual or computer-assisted guidance for tunnel placement with follow-up at 1, 3, 6, 12, 18, and 24 months. There were no differences between the groups in measurements of laxity. However, there was less variability in side-to-side
anterior laxity in the navigated group (e.g., 97% were within 2 mm of laxity in the navigated group vs. 83% in the conventional group at an applied force of 150 N). There was a significant difference in the sagittal position of the tibial tunnel (distance from the Blumensaat line of 0.4 mm vs. -1.2 mm, respectively), suggesting possible impingement in extension for the conventional group. At the final follow-up (24 months), all knees had normal function, with no differences observed between the groups.

Hart and colleagues compared biomechanical radiographic and functional results in patients randomized to ACL reconstruction using CAN (n=40) or the standard manual targeting technique (n=40). Blinded evaluation found more exact bone tunnel placement with CAN but no overall difference in biomechanical stability or function between the groups.

Other studies have found no significant improvement in the accuracy of tunnel placement when using CAN. In 2012, the authors of the 2011 Cochrane review reported a double-blind controlled trial with 100 patients who were randomly assigned to either conventional or computer-assisted surgery. Evaluation by 3-dimensional computed tomography (CT) found no significant difference between the 2 groups for either the accuracy or the precision of the femoral and tibial tunnel placement.

Another study randomized 53 patients to manual or computer-assisted ACL reconstruction by 3 experienced surgeons (at least 1,000 cruciate ligament operations). Tunnel placement and range variance were similar for the 2 groups; indicating that experienced surgeons can achieve essentially the same positioning as CAN.

**Section Summary: Anterior or Posterior Cruciate Ligament Reconstruction**

The evidence on CAN for ACL or PCL reconstruction includes a systematic review of 5 RCTs. These RCTs, of moderate to low quality, did not consistently demonstrate more accurate tunnel placement with CAN. No studies have shown an improvement in functional outcomes or need for revision when CAN is used for ACL or PCL reconstruction.

**Hip Arthroplasty and Periacetabular Osteotomy**

Few RCTs have evaluated CAN for hip procedures.

**Total Hip Arthroplasty**

Paratte and Argenson randomized patients to CAN for THA (n=30) or freehand cup positioning (n=30) by an experienced surgeon. The mean additional time for the computer-assisted procedure was 12 minutes. There was no difference between the computer-assisted group and the freehand-placement group with regard to the mean abduction or anteversion angles measured by CT. A smaller variation in the positioning of the acetabular component was observed in the CAN group; 20% of cup placements were considered to be outliers in the CAN group compared with 57% in the freehand-placement group. In a randomized trial of 125 patients, Lass and colleagues compared the acetabular component position between CAN and the conventional freehand technique. CT scans identified higher accuracy for acetabular component anteversion, deviation from the target position for anteversion, and in outliers from the target for inclination and anteversion. The operation time was 18 minutes longer for CAN. Functional outcomes were not assessed.
A 2011 study by Manzotti and colleagues compared leg length restoration in a matched-pair study. Forty-eight patients undergoing THA with CAN were with patients who were matched for age, sex, arthritis level, preoperative diagnosis, and preoperative leg compared length discrepancy and underwent conventional freehand THA using the same implant in the same period. The mean preoperative leg length discrepancy was 12.17 mm in the THA-CAN group and 11.94 in the standard THA group. Surgical time was increased by 16 minutes (89 min vs. 73 min, respectively). There was a significant decrease in both the mean postoperative leg length discrepancy (5.06 mm vs. 7.65 mm) and in the number of cases with a leg length discrepancy of equal to or greater than 10 mm (5 patients vs. 13 patients, all respectively). Outcomes at 40-month follow-up (range, 7-77 months) were not significantly different for the Harris Hip Score (88.87 vs. 89.73) or the 100-point normalized Western Ontario and McMaster Universities (WOMAC) Arthritis Index (9.33 vs. 13.21, all respectively; p=0.0503). Longer follow-up with a larger number of subjects is needed to determine whether THA-CAN influences clinical outcomes.

Minimally Invasive THA

It has been proposed that CAN may overcome the difficulties of reduced visibility of the surgical area associated with minimally invasive procedures. A 2007 review by Ulrich and colleagues summarized studies that compared outcomes from minimally invasive THA-CAN and standard THA. Seventeen studies were described in this evidence-based review, including 9 prospective comparisons, 7 retrospective comparisons, and 1 large (n=100) case series. The review concluded that alignment with minimally invasive CAN appears to be at least as good as standard THA, although the more consistent alignment must be balanced against the current expense of the computer systems and increased surgical time. Improved health outcomes have not yet been demonstrated with CAN or minimally invasive THA, either alone or in combination.

Short-term outcomes of minimally invasive THA approach with CAN (n=35) compared to conventional posterolateral THA (n=40) was reported by Reninga and colleagues in 2013. This randomized comparison found no group differences in the recovery of gait at up to 6 months after surgery.

Periacetabular Osteotomy with CAN

A 2006 study randomly assigned 36 patients with symptomatic adult dysplastic hip to either CT-based navigation or the conventional technique for periacetabular osteotomy. An average of 0.6 intraoperative radiographs were taken in the navigated group compared with 4.4 in the conventional group, resulting in a total operative time that was 21 minutes shorter for CAN. There were no differences between the groups for correction in femoral head coverage or for functional outcomes (pain, walking, range of motion) at 24 months.

Total Hip Resurfacing (THR) with CAN

In 2013, Stiehler and colleagues reported short-term radiographic and functional outcomes from a randomized comparative trial of CAN-THR (total hip resurfacing) in 75 patients. For most of the radiographic measures, there was no significant difference between the CAN and conventional THR groups. There were fewer outliers (≥5°) for the femoral component with CAN (11%) compared with conventional placement (32%). At 6-month follow-up, there were no differences between groups in
the final WOMAC or Harris Hip Score. The CAN group did show a greater percentage improvement in the WOMAC and Harris Hip Score due to differences between the groups at baseline.

**Section Summary: Hip Arthroplasty and Periacetabular Osteotomy**

Relatively few RCTs have evaluated CAN for hip procedures. Although there was early interest in this technology, no recent RCTs have been identified. There is inconsistent evidence from these small trials on whether CAN improves alignment with conventional or minimally invasive THA. One RCT found improved alignment when CAN was used for hip resurfacing, but there was little evidence of improved

**Total Knee Arthroplasty**

Alignment of a knee prosthesis can be measured along several different axes, including the mechanical axis, and the frontal and sagittal axes of both the femur and tibia.

**Systematic Reviews**

A 2007 TEC Assessment evaluated CAN for TKA. Nine studies from 7 randomized controlled trials (RCTs) were reviewed. Criteria for the RCTs included having at least 25 patients per group and comparing limb alignment and surgical or functional outcomes following TKA with CAN or conventional methods. Also reviewed were cohort and case series that evaluated long-term associations between malalignment of prosthetic components and poor outcomes. In the largest of the cohort studies, which included more than 2,000 patients (3,000 knees) with an average of 5-year follow-up, 41 revisions for tibial component failure (1.3% of the cohort) were identified. The risk ratio for age was estimated at 8.3, with a greater risk observed in younger, more active patients. For malalignment (defined as >3° varus or valgus), the risk ratio was estimated to be 17.3.

The combined data from the prospective RCTs showed:

- A significant decrease in the percentage of limbs considered to be outliers (e.g., >3° of varus or valgus from a neutral mechanical axis) with CAN. In the conventional group, 33% of patients had malalignment of the overall femoral/tibial axis. In the navigated group, 18% of patients were considered to have malalignment of the mechanical axis. For the combined data set, there was a decrease in malalignment in 15% of patients, with an estimated number needed to treat of 6.7 to avoid 1 case of malalignment.
- Surgical time increased by 10 to 20 minutes in all but 1 study. CAN-associated reduction in blood loss was less consistent, with only some of the studies showing a decrease in blood loss of 100 to 200 mL.
- RCTs that assessed function (up to 2 years of follow-up) did not find evidence of improved health outcomes. However, the studies were not adequately powered to detect functional differences, and data on long-term follow-up were not available.

As a result of deficiencies in the available evidence (e.g., potential for bias in observational studies and lack of long-term follow-up in the RCTs), it was not possible to determine whether the degree of improvement in alignment that has been reported in the RCTs leads to meaningful improvements in clinically relevant outcomes such as pain, function, or revision surgery.

A 2012 meta-analysis included 21 randomized trials (total N=2658 patients) that reported clinical outcomes with or without the use of CAN. Most studies included in the review had short-term
follow-up. As was found in the 2007 TEC Assessment, surgical time was significantly increased with CAN for TKA, but there was no significant difference between approaches in total operative blood loss, the Knee Society Score (KSS), or range of motion. Rebal et al (2014) conducted a meta-analysis of 20 RCTs (total N=1713 knees) that compared imageless navigation technology with conventional manual guides. Nine studies were considered to have a low risk of bias due to the blinding of patients or surgical personnel. Fifteen studies were considered to have a low risk of bias due to evaluator blinding. The improvement in KSS was statistically superior in the CAN group at 3 months (4 studies; 68.5 vs 58.1, p=0.03) and at 12 to 32 months (5 studies; 53.1 vs 45.8, p<0.01). However, these improvements did not achieve the minimal clinically significant difference, defined as a change of 34.5 points.

More recent studies have also found a longer surgical time and little difference in clinical outcome measures at 1-year follow-up.

**Effect of CAN on Mid- to Long-term Outcomes**

Most studies comparing outcomes at mid- to long-term generally show a reduction in the number of outliers with CAN, but little to no functional difference between the CAN and conventional TKA groups.

Follow-up from 4 randomized trial were published in 2013 to 2015 that assessed mid-term functional outcomes following CAN for TKA. Blakeney and colleagues reported 46-month follow-up of 107 patients from a randomized trial of CAN versus conventional surgery. There was a trend toward higher scores on the Oxford Knee questionnaire with CAN, with a mean score of 40.6 for the CAN group compared with 37.6 and 36.8 in extramedullary and intramedullary control groups. There was no significant difference in the 12-Item Short-Form Health Survey Physical Component or Mental Component Summary scores. The trial was underpowered, and the clinical significance of this trend for the Oxford Knee questionnaire is unclear.

Lutzner and colleagues reported 5-year follow-up in 67 of 80 patients randomized to CAN or conventional TKA. There was a significant decrease in the number of outliers with CAN (3 vs. 9, p=0.048), but no significant differences between the groups on the KSS or EuroQoL questionnaire for quality of life. Cip and colleagues found a significant decrease in malalignment with CAN, but no significant differences in implant survival or consistent differences clinical outcome measures between the navigated (n=100) and conventional (n=100) TKA groups at minimum 5-year follow-up. The trial, which assessed 80 patients (88 knees) was powered to detect a 3-point difference in KSS results.

Other comparative study designs have found no significant differences in clinical outcomes following CAN. In a 2009 comparative study of 160 bilateral TKAs performed by experienced surgeons in Asia, differences in measures of alignment between the conventionally prepared knee and the knee prepared with CAN-assistance were minimal. In 2012, this group reported longer term follow-up (mean, 10.8 years) on 520 patients who underwent CAN for one knee and conventional TKA for the other knee (randomized). There were no significant differences between the groups for knee function or pain measures. Kaplan-Meier survivorship at 10.8 years was 98.8% in the CAN knee and 99.2% for the conventional knee. Two additional nonrandomized comparative
studies from 2012 found an improvement in alignment with CAN, but no difference in clinical or functional outcomes at 5-year follow-up when compared with conventional TKA.

Hoffart and colleagues used alternate allocation of 195 patients to compare functional outcomes following CAN-assisted TKA versus conventional instrumentation. An independent observer performed the pre- and postoperative assessments. After 5 years, 18 patients (9.2%) were lost to follow-up and complete clinical scores were available for 121 patients (62%). There was no significant difference in the frequency of malalignment between the 2 groups. The CAN group had a better mean KSS and mean function and knee scores. Mean pain scores did not differ between the 2 groups. Limitations of this study include the high loss to follow-up and lack of subject blinding.

In 2016, Dyrhovden and colleagues compared survivorship and the relative risk of revision at 8-year follow-up for 23,684 cases from the Norwegian Arthroplasty Register. Overall prosthesis survival and risk of revision were similar for the 2 groups, although revisions due to malalignment were reduced with CAN (RR=0.5; 95% CI, 0.3 to 0.9; p=0.02). There were no significant differences between the groups for other reasons for revision (eg, aseptic loosening, instability, periprosthetic fracture, decreased range of motion). At 8 years, the survival rate was 94.8% (95% CI, 93.8% to 95.8%) in the CAN group and 94.9% (95% CI, 94.5% to 95.3%) for conventional surgery.

Section Summary: Total Knee Arthroplasty
A large number of RCTs have compared outcomes between TKA with CAN and conventional TKA without CAN. Results are consistent in showing a reduction in the proportion of outliers greater than 3° in alignment. Results up to 10 years postoperatively have not shown that these differences in alignment lead to improved patient outcomes.

Summary of Evidence
For individuals who are undergoing orthopedic surgery for trauma or fracture, ligament reconstruction, hip arthroplasty and periacetabular osteotomy, or total knee arthroplasty who receive computer-assisted navigation (CAN), the evidence includes randomized controlled trials (RCTs) and nonrandomized comparative studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Overall, the literature supports a decrease in variability of alignment with CAN, particularly with respect to the number of outliers. Although some observational data have suggested that malalignment may increase the probability of early failure, recent RCTs with short- to mid-term follow-up have not shown improved clinical outcomes with CAN. Given the low short-term revision rates associated with conventional procedures and the inadequate power of the available studies to detect changes in function using CAN, studies are needed that assess health outcomes using CAN in a larger number of subjects with longer follow-up to permit greater certainty on the impact of this technology. The evidence is insufficient to determine the effects of the procedure on health outcomes.

Supplemental Information
Clinical Input From Physicians Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 academic medical centers while this policy was under review in 2011. The input was mixed on whether computer-assisted navigation is considered investigational. One reviewer provided additional references on high tibial osteotomy and pelvic tumor resection.

Due to the lack of any recent studies on pelvic tumor resection, these sections of the Rationale were removed from this evidence review in 2016.

**Practice Guidelines and Positions Statements**

No guidelines or statements were identified.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination (NCD). **Ongoing and Unpublished Clinical Trials**

One currently unpublished trial that might influence this policy is listed in Table 1.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>Ongoing</td>
<td>NCT01469299&lt;sup&gt;a&lt;/sup&gt; Prospective Study Measuring Clinical Outcomes of Knee Arthroplasty Using the VERASENSE™ Knee System</td>
<td>500</td>
<td>Dec 2015</td>
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</table>

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

**V. Important Reminder**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with
HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References


