7.01.96	Computer-Assisted Musculoskeletal Surgical Navigational OrthopedicProcedure	
Section 7.0 Surgery	**Effective Date** September 30, 2014	
Subsection	**Original Policy Date** June 26, 2009	**Next Review Date** September 2015

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.

Related Policies

- Robotic Assisted Surgical Procedures

Policy

Computer-assisted surgery for orthopedic procedures of the pelvis and appendicular skeleton is considered **investigational**.

Policy Guidelines

Coding

The coding for this navigation includes one category I CPT code and 2 category III CPT codes :

- **20985**: Computer-assisted surgical navigational procedure for musculoskeletal procedures; image-less (List separately in addition to code for primary procedure)

- **0054T**: Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image guidance based on fluoroscopic images (List separately in addition to code for primary procedure)

- **0055T**: Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image guidance based on CT/MRI images (List separately in addition to code for primary procedure)

All of the codes are intended to be used in addition to the code for the primary procedure.

Note: Reimbursement for the technical component of computer-assisted navigation may be sought either through the use of the CPT codes listed here, or through hospital case rates.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.
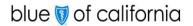
Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

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 (ACL).

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 (OR), 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 anatomic 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 OR.

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." FDA product code: haw.

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 intra-operatively (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."

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

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 1 plane. Therefore, the surgeon must position the implant in 1 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 (OR) 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 OR 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,(1-3) a literature review at the time this policy was created identified only 1 clinical trial of computer-assisted surgery in trauma or fracture cases. (4) 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. (5) 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). Additional controlled studies are needed.

Anterior Cruciate Ligament or Posterior Cruciate Ligament Reconstruction

A 2011 Cochrane review assessed the effects of CAN in comparison with conventional operating techniques for anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) reconstruction. (6) Four randomized controlled trials (RCTs; 266 participants) on ACL reconstruction were included in the review; no studies involved PCL reconstruction. Pooled data from 2 trials showed no statistically or clinically significant differences in self-reported health outcomes (International Knee Documentation Committee [IKDC] subjective scores and Lysholm scores) at 2 years or more follow-up. A third trial included in this review found a small statistically significant difference in IKDC subjective scores. No significant differences were found for objective measures of knee function, including the IKDC examination grade and pivot shift test. Evaluation of bias and methodologic quality was limited by poor reporting of trial methods. Overall, there was insufficient evidence to advise for or against the use of CAN. Three of the 4 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. (7) 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 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 et al (2008) compared biomechanical radiographic and functional results in patients randomized to ACL reconstruction using CAN (n=40) or the standard manual targeting technique (n=40). (8) 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. (9) 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 1000 cruciate ligament operations). (10) Tunnel placement and range variance were similar for the 2 groups; indicating that experienced surgeons can achieve essentially the same positioning as CAN.

Arthroplasty of the Hip and Knee

For both total hip arthroplasty (THA) and total knee arthroplasty (TKA), optimal alignment is considered an important aspect of long- term success. Malalignment of arthroplasty components is one of the leading causes of instability and reoperation. In THA, orientation of the acetabular component of the THA is considered critical, while for TKA, alignment of the femoral and tibial components and ligament balancing are considered important outcomes. The alignment of the 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. It is proposed that computer-assisted surgery improves the alignments of the various components of THA and TKA. Ideally, one would like controlled trials comparing the long-term outcomes, including stability and reoperation rates.

Intermediate outcomes include the percentage of implants that achieve a predetermined level of acceptable alignment.

Hip Arthroplasty and Periacetabular Osteotomy

Paratte and Argenson (2007) randomized patients to CAN for THA (n=30) or freehand cup positioning (n=30) by an experienced surgeon. (11) 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 et al (2014) compared the acetabular component position between CAN versus the conventional freehand technique. (12) 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 study by Manzotti et al (2011) compared leg length restoration in a matched-pair study. (13) Forty-eight patients undergoing THA with CAN were compared with patients who were matched for age, sex, arthritis level, preoperative diagnosis, and preoperative leg 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 vs. 73 min, respectively). There was a significant decrease in both the mean postoperative leg length discrepancy (5.06 vs. 7.65 mm) and in the number of cases with a leg length discrepancy of 10 mm or more (5 vs. 13 patients – all respectively). Outcomes at 40-month follow-up (range, 7 to 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=0.050). Longer follow-up with a larger number of subjects is needed to determine whether THA-CAN influences clinical outcomes.

Minimally Invasive THA With CAN

It has been proposed that CAN may overcome the difficulties of reduced visibility of the surgical area associated with minimally invasive procedures. A review by Ulrich et al (2007) summarized studies that compared outcomes from minimally invasive THA-CAN and standard THA. (14) 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 with conventional posterolateral THA (n=40) (Reninga et al, 2013). (15) 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.

(16) 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 With CAN

Stiehler et al (2013) reported short-term radiographic and functional outcomes from a randomized comparative trial of CAN-THR (total hip resurfacing) in 75 patients. (17) 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.

Total Knee Arthroplasty

Systematic Reviews

A 2007 TEC Assessment evaluated CAN for TKA. (18) Nine studies from 7 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 2000 patients (3000 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 (RR) 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 RR 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' 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 are not available.

The report concluded that no direct evidence is currently available to support an improvement in clinical outcomes with CAN for TKA. 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 meta-analysis of CAN for TKA was reported in 2007 that included 33 studies and 3423 patients. (19) The studies were of varying methodologic quality and included 11 randomized trials. Although no significant difference in mechanical axes between the navigated and conventional surgery group was found, navigated surgery was found to result in a lower risk of malalignment. It was calculated that 1 of every 5 patients would avoid unfavorable component positioning (>3°) with CAN. Methodologic weaknesses of the available trials limited the conclusions of the meta-analysis, and no conclusive inferences could be reached for functional outcomes or complication rates. A 2012 meta-analysis included 21 randomized trials (2658 patients) that reported clinical outcomes with or without the use of CAN. (20) Most of the studies included in the review had short-term follow-up. Operative time was significantly increased with CAN for TKA. There was no significant difference 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 (1713 knees) that compared imageless navigation technology with conventional manual guides. (21) Nine studies were considered to have a low risk of bias due to the blinding of the patient 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); the minimal clinically significant difference was defined as a change of 34.5 points.

Gothesen et al (2014) reported 1-year follow-up from a double-blinded trial of 192 patients randomized to CAN or conventional TKA. (22). CAN took 20 minutes longer than conventional surgery and led to significantly fewer outliers in frontal alignment and tibial slope. Statistically significant improvements with CAN were found on the Knee Injury and Osteoarthritis Outcome Score (KOOS) sports (mean difference, 11.0; p=0.007) and KOOS symptoms (mean difference, 6.7; p=0.035), but not for KOOS pain, KOOS quality of life, visual analog scale (VAS), or KSS. Only the KOOS subscale for sports and recreational activities exceeded the predefined minimal important change.

Effect of CAN on Mid- to Long-term Outcomes

Most studies comparing outcomes between CAN and conventional TKA at mid- to long-term generally show a reduction in the number of outliers with CAN, but little to no functional difference between the 2 groups.

Follow-up from 2 randomized studies were published in 2013/2014 that assessed mid-term functional outcomes following CAN for TKA. Blakeney et al (2014) reported 46-month follow-up of 107 patients from a randomized trial of CAN versus conventional surgery. (23) 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 Scores. The study was underpowered, and the clinical significance of this trend for the Oxford Knee questionnaire is unclear. Lutzner et al (2013) reported 5-year follow-up in 67 of 80 patients randomized to CAN or conventional TKA. (24) 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.

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. (25) In 2012, this group reported longer term follow-up (mean, 10.8 years) on 520 patients who underwent CAN for 1 knee and conventional TKA for the other knee (randomized). (26) 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. (27,28)

Ishida et al (2011) compared 30 patients who had TKA-CAN with 30 matched patients who had the same implant type by the same surgeon during the same period of time using the standard manual approach. (29) At 5- to 7-year follow-up, the accuracy of the implantations, evaluated by 2 investigators who were blinded to clinical information, was significantly better in the TKA-CAN group for both the mechanical axis (18.5% vs. 33.3% outliers) and femoral rotational alignment (2° vs. 4° twist angle – both respectively). Clinical assessment by an independent observer found superior range of motion (120° vs. 105°) and Knee Society Scores (94 vs. 84 points – both respectively) in the TKA-CAN group. However, there was no difference between groups in pain (50 vs. 50 points) or Knee Society Functional scores (80 vs. 80 points – both respectively) at final follow-up.

Hoffart et al (2012) used alternate allocation of 195 patients to compare functional outcomes following CAN-assisted TKA versus conventional instrumentation. (30) 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.

Effect of Alignment on Mid- to Long-term Outcomes

Huang et al (2012) reported 5-year follow-up of a 2009 randomized trial. (31,32) In the initial report, a greater accuracy in implant alignment was associated with better knee function and quality of life. Of the original 115 patients, 90 (78%) were available for follow-up at 5 years. Of these, coronal alignment was within 3° of neutral in 69 patients (91% of CAN patients vs. 61% of conventional) and greater than 3° in 21 patients (9% of CAN patients vs. 39% of conventional). Patients with coronal alignment within 3° of normal scored significantly higher on the KSS at 2 years (median, 162 vs. 131) and 5 years (142 vs. 129). This study is unusual in that the investigators compared outcomes based on alignment, rather than comparing outcomes from the CAN and conventional TKA groups.

Several nonrandomized or quasirandomized studies have examined the association between alignment and clinical outcomes at mid- to long-term follow-up. Czurda et al (2010) compared outcomes from a consecutive series of 411 patients who underwent TKA-CAN (n=146) with the TC-PLUS SB Solution™ (Smith and Nephew) or standard TKA (n=265) with the LCS® Complete Mobile Bearing Knee System (DePuy). (33) Patients were interviewed by telephone by a single assessor and were classified as having painful knees if they listed pain as moderate or worse. At 11- to 41-month follow-up, median WOMAC scores were the same for both groups. Fifteen patients (12%) in the TKA-CAN group and 42 patients (20%) in the standard arm had moderate to severe pain (p=0.06). To further evaluate the relationship between pain and alignment, a second part of the study compared a subset of 19 patients that had painful knees with matched patients who had asymptomatic knees. Radiographic and CT analysis was performed for these 38 case-control subjects. There was no significant relationship between postoperative pain and the mechanical axis, flexion of the femoral component, or the dorsal slope. There was a trend for an association between patellar tracking and pain (odds ratio [OR], 3.5; p=0.10) and a significant association between incorrect rotational malalignment and pain (OR=7; p=0.033).

A retrospective study by Parratte et al (2010) assessed the influence of mechanical axis alignment on 15-year survival in 280 patients who received a standard cemented TKA between 1985 and 1990. (34) A total of 106 of 398 TKAs were found to have a postoperative mechanical axis of greater than 3°. At the latest follow-up, there were a lower proportion of revisions in the outlier group than in the aligned group (13% vs. 15.4%, respectively). When comparing revisions due to aseptic loosening mechanical failure, wear, or patellar problems, 7.5% of the outlier group were revised compared with 9.2% of the aligned group. Thus, a postoperative mechanical axis of 0°±3° did not improve the 15-year survival rate following modern TKA.

Learning Curves

Carter et al (2008) compared outcomes from TKA in consecutive patients before and after acquisition of a CAN system in a community hospital. (35) Of 310 consecutive surgeries, 200 patients (100 CAN, 100 conventional) consented to follow-up with a CT scan. Results were considered good if alignment was 3° or less from the surgical goal, fair if between 4° and 6°, poor if between 7° and 9°, and extremely poor if greater than 9° from the surgical goal. Blinded evaluation rated sagittal alignment as good in 78% of CAN and 47% of conventional knees for the femoral component and in 93% of CAN and 64% of conventional knees for the tibial component. Thirteen knees had poor or extremely poor sagittal-tibial alignment in the conventional group. Coronal alignment was not significantly different between the groups, although variance was greater in the conventional group. Tibial rotation was inconsistent in both groups. No learning curve was observed for the accuracy of alignment, although the initial cases required 12 to 20 minutes in additional time. By the end of the series, the highest volume surgeon required less time for CAN than for the conventional approach. Learning curves were also addressed in a prospective controlled observational study from 13 European orthopedic centers. (36)

Computer-Assisted Gap Balancing

Pang et al (2011) evaluated the functional outcome of computer-assisted gap balancing (soft tissue balance) compared with conventional measured resection in TKA. (37) A total of 140 patients were randomized into the 2 groups, and both patients and postoperative evaluators were blinded to treatment assignment. At 2 years, there were significantly more patients in the conventional group with flexion contracture of more than 5° (7% vs. 1%). There was no significant difference between groups in hyperextension or ligament laxity. There was no significant difference between groups in the knee score, function score, or 36-Item Short-Form Health Survey. At the 2-year follow-up, the CAN group had better outcome in the Total Oxford Score (16.4 vs. 19.1). Interpretation of this finding is limited, because the postoperative Oxford Score did not differ from the preoperative score with CAN (16.4 vs. 16.3), and the 2-year differences result from worsening scores in the conventional treatment group. Additional study is needed to determine with greater certainty whether flexion contracture is reduced with computer-assisted gap balancing.

Computer-Assisted Minimally Invasive TKA

It has been proposed that CAN may overcome the difficulties of reduced visibility associated with minimally invasive procedures. In 1 study, 108 consecutive patients were randomized to computer-assisted "minimally invasive" TKA or conventional TKA with standardized perioperative pain management for both groups. (38) An independent physical therapist performed the preoperative and postoperative patient assessments. Operative time was found to increase by an average of 24 minutes with minimally invasive CAN, with a difference in incision length of 4 cm (9 cm vs. 13 cm). Alignment

was at 3° or less from target in 92% of patients for the coronal tibiofemoral angle, 90% for the sagittal tibial component angle. This compared with 68% and 61%, respectively, for patients in the conventional TKA group. Three other measured angles were not significantly different. There was no difference in postoperative pain between the groups. Hospital stay, based on standardized functional criteria for discharge, was an average 1.2 days shorter (3.3 vs. 4.5 days). Functional improvement was noted at 1 month postoperatively for the number of patients who could walk independently for 30 minutes (details not reported). At 6 months, functional outcomes were similar for the 2 groups.

Luring et al (2008) published results from a 3-arm randomized trial (30 patients per group) that compared minimally-invasive TKA, with or without CAN, and conventional TKA. (39) In this study, the mini-incision averaged 13 cm (range, 10-14 cm), while the conventional midline incision averaged 17 cm (range, 15-19 cm); both were performed with a medial parapatellar approach. In addition, with the minimally-invasive procedure, there was subluxation rather than eversion of the patella and no tibiofemoral dislocation. Postoperative rehabilitation and hospital stay were not described. On average, the surgical procedure took longer in the computer-assisted minimally invasive surgery group (58 minutes) compared with the conventional (44 minutes) and freehand minimally invasive surgery group (40 minutes) and was associated with greater blood loss. Independent evaluation of postoperative radiographs showed reduced deviation in mechanical axis alignment in the CAN group (1.0°) compared with both the freehand minimally invasive group (1.8°) and the conventional TKA group (2.1°). Compared with 3 outliers in the freehand minimally-invasive group and 2 outliers in the conventional TKA group, no outliers greater than 3° were observed in the computer-assisted minimally invasive group. Follow-up (100%) with KSS and WOMAC at 1, 6, and 12 weeks revealed no differences between the 3 groups. Because there was no statistically significant clinical difference at 6 or 12 weeks, the planned 6- and 12-month follow-up was stopped. According to patient satisfaction (WOMAC) and clinical outcome (KSS), the minimally invasive approach in TKA is still not proven.

Section Summary

There are a large number of randomized and nonrandomized trials that have compared outcomes between CAN-TKA and conventional TKA. Results are consistent in showing a reduction in the proportion of outliers greater than 3° in alignment. Results up to 10 years postoperatively are inconsistent regarding whether these differences in alignment lead to improved patient outcomes.

High Tibial Osteotomy

Bae et al (2009) compared the accuracy of closed-wedge high tibial osteotomy using CAN for medial compartment osteoarthritis of the knee and genu varum (n=50) with historical controls (n=50) that had undergone high tibial osteotomy using the conventional technique. (40) The navigation system provided information about the deformity, level of osteotomy, correction angle and wedge size. In the conventional group, correction angle and wedge size were determined from a preoperative radiologic plan and intraoperative measurement with the help of a cable. All of the cases had good quality preoperative and follow-up radiographs, and measurements were assessed by 2 independent investigators. The preoperative mechanical axis in the navigation group was varus 8.2° with the navigation system and 7.3° on radiographs. The mean postoperative mechanical axis was valgus 3.6° with the navigation system and valgus 2.1° with radiographs. The mean difference in the postoperative mechanical axis for the 2 measurements was 1.5°. Compared with the conventional group, the variability of postoperative mechanical axis was significantly lower (2.3° vs. 3.7°, respectively). There were 19 cases of a mechanical axis between 2° and 6° in the conventional group

compared with 2 cases in the navigated group. This study did not evaluate if the decrease in variability in the navigated group improved clinical outcomes.

Pelvic Tumor Resection

A 2009 review of the literature on computer-assisted pelvic tumor resection suggests that predefined osteotomy planes can be successfully identified during the operation and that planned surgical margins can be achieved. (41) The number of cases is small, and no controlled studies were identified that compared outcomes with conventional surgical approaches. However, inadequate (contaminated or intralesional) surgical margins have been reported in 12% to 75% of conventional cases. The authors note that the preoperative process for CAN is time-consuming, due to the lack of commercially available navigation platforms for pelvic applications.

Ongoing Clinical Trials

A search of online site www.ClinicalTrials.gov identified a prospective observational cohort study on the Orthosensor Surgical Smart Trial (NCT01469299). This study will evaluate outcomes from soft tissue balancing with the Orthosensor in comparison with soft tissue balancing by feel. The study has an estimated enrollment of 500 patients. The estimated primary completion date is December 2015.

Summary

Overall, the literature supports a decrease in variability of alignment with computer-assisted navigation (CAN), particularly with respect to the number of outliers. Although some observational data suggest that malalignment may increase the probability of early failure, recent randomized controlled trials with short- to mid-term follow-up have not shown improved health outcomes with CAN. Given the low short-term revision rates associated with conventional procedures and the inadequate power of available studies to detect changes in function, studies that assess health outcomes in a larger number of subjects with longer follow-up are needed. Potential uses of this procedure may be in gap balancing and the ability to decrease incision length without loss of accuracy in component alignment. Another area of potential benefit is pelvic tumor resection. Although evidence at this time has not adequately demonstrated improved health outcomes with this more resource-intensive combination, continued technology development in this area is expected.

U.S. Preventative Service Task Force Recommendations

Computer assisted musculoskeletal orthopedic surgery is not a preventive service.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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Documentation Required for Clinical Review
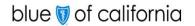
- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

Type	Code	Description
CPT®	0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure)
	0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (List separately in addition to code for primary procedure)
	20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (List separately in addition to code for primary procedure)
HCPC	None	
ICD-9 Procedure	None	
ICD-10	*For dates of service on or after 10/01/2015*	

Procedure	8E09XBZ	Computer Assisted Procedure of Head and Neck Region
	8E0WXBZ	Computer Assisted Procedure of Trunk Region
	8E0XXBZ	Computer Assisted Procedure of Upper Extremity
	8E0YXBZ	Computer Assisted Procedure of Lower Extremity
ICD-9 Diagnosis	All Diagnoses	
ICD-10 Diagnosis	*For dates of service on or after 10/01/2015*	
	All Diagnoses	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.
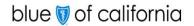
Effective Date	Action	Reason
8/12/209	Coding Update	Administrative Review
6/26/2009	New Policy Adoption	Medical Policy Committee
1/6/2012	Policy revision without policy change	Medical Policy Committee
9/30/2014	Policy title change from Computer-Assisted Navigation for Orthopedic Surgery Policy revision without policy change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

blue of california

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.