BlueCross BlueShield of Alabama

Name of Policy:
Computer-Assisted Navigation for Orthopedic Procedures

Policy #: 229
Category: Surgery

Latest Review Date: May 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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.

Computer-Assisted Navigation

The goal of CAN is to increase surgical accuracy and reduce the chance of malposition. For total knee arthroplasty (TKA), malalignment is commonly defined as variation of greater than three degrees 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, computer navigation 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 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 three-dimensional 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 three steps described below: data acquisition, registration, and tracking.

Data Acquisition

Data can be acquired in three different ways: fluoroscopic, CT/MRI-guided, or imageless systems. This data is then used for registration and tracking.

Registration

Registration refers to the ability of relating images (i.e., x-rays, CT, MRI, or patients' 3-D 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 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 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 on 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.

Policy:

Computer-assisted surgical navigation when used as an adjunct to orthopedic procedures, including but not limited to the pelvis and appendicular skeleton **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The policy has been updated regularly using the MEDLINE database. The most recent literature update was performed through February 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function- including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

For many orthopedic surgical procedures, optimal alignment is considered an important aspect of long-term success. For example, misplaced tunnels in the 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), the 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.

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. The surgeon must then 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 OR time and radiation exposure. It is hoped that 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, a literature review 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 two

cohorts of consecutive patients (20 each, performed from 2001 to 2003 at two different campuses of a medical center) who underwent internal fixation with three screws for a femoral neck fracture. Three of five 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 degrees) and the fracture (1.7 vs 5.5 degrees, all respectively) screw angles. Slight improvements in anteroposterior screw angles (1.3 vs 2.1 and 1.3 vs 2.4 degrees, respectively) did not reach statistical significance. There were two reoperations in the CAN group and six 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 or Posterior Cruciate Ligament Reconstruction

A 2014 Cochrane review assessed the effects of CAN in comparison with conventional operating techniques for ACL or PCL reconstruction. Five randomized controlled trials (RCTs, 366 participants) on ACL reconstruction were included in the updated review; no studies involved PCL reconstruction. The quality of evidence ranged from moderate to very low. Pooled data showed no statistically or clinically significant differences in self-reported health outcomes (International Knee Documentation Committee [IKDC] subjective scores and Lysholm scores) at two years or more 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 five trials included in the Cochrane review are described below.

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 2mm of laxity in the navigated group versus 83% in the conventional group at an applied force of 150 Newtons). There was a significant difference in the sagittal position of the tibial tunnel (distance from the Blumensaat line of 0.4 vs. -1.2mm, 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 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 two 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 three experienced surgeons (at least 1000 cruciate ligament operations). Tunnel placement and range variance were similar for the two 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. The RCTs, of moderate to low quality, have not consistently demonstrated 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
There are few RCTs that have evaluated CAN for hip procedures.

Total Hip Arthroplasty
In a 2007 study, 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 2014 randomized trial of 125 patients, Lass et al compared the acetabular component position between CAN versus 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 et al compared leg length restoration in a matched-pair study. 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 12.17mm 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 7.65mm) and in the number of cases with a leg length discrepancy of 10mm 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=0.0503). 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 2007 review by Ulrich et al summarized studies that compared outcomes from minimally invasive THA-CAN and standard THA.

Seventeen studies were described in this evidence-based review, including nine prospective comparisons, seven retrospective comparisons, and one 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.

Short-term outcomes of minimally invasive THA approach with CAN (n=35) compared with conventional posterolateral THA (n=40) was reported by Reninga et al in 2013. This randomized comparison found no group differences in the recovery of gait at up to six months after surgery. Improved health outcomes have not yet been demonstrated with CAN or minimally invasive THA, either alone or in combination.

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 et al 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 degrees) for the femoral component with CAN (11%) compared with conventional placement (32%). At six months' 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 regarding 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 outcomes at short-term follow-up. Overall, improved health outcomes have not been demonstrated with CAN for any hip procedures.

Total Knee Arthroplasty

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.

Systematic Reviews

A 2007 TEC Assessment evaluated CAN for TKA. Nine studies from seven 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 five-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 degrees 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 degrees of varus or valgus from a neutral mechanical axis) with CAN.
- Surgical time increased by 10 to 20 minutes in all but one 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 200mL.
- RCTs that assessed function (up to two 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.

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 (2658 patients) that reported clinical outcomes with or without the use of CAN. Most of the studies included in the review had short-term follow-up. As was found in the 2007 TEC Assessment, 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 conducted a 2014 meta-analysis of twenty RCTs (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 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 three months (four studies, 68.5 vs 58.1, $p=0.03$) and at 12 to 32 months (five studies, 53.1 vs 45.8, $p<0.01$). However, this did not achieve the minimal clinically significant difference was 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 one year follow-up.

Effect of CAN on Mid- to Long-Term Outcomes

Most studies comparing outcomes 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 four randomized studies were published in 2013 to 2016 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. 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 study was underpowered, and the clinical significance of this trend for the Oxford Knee questionnaire is unclear.

Lutzner et al (2013) reported five-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 Euroquol questionnaire for quality of life. Cip et al (2014) 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 five year follow-up. Song et al (2016) also reported a reduction in the number of outliers with CAN (n=80, 7.3% vs 20%, p=0.006), with no significant differences in clinical outcomes at 8-year follow-up. The study was powered to detect a 3-point difference in KSS results.

Other comparative study designs have also 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 of 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 five-year follow-up when compared with conventional TKA.

Hoffart et al (2012) 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 five 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 two groups. The CAN group had a better mean KSS and mean function and knee scores. Mean pain scores did not differ between the two groups. Limitations of this study include the high loss to follow-up and lack of subject blinding.

In 2016, Dyrhovden et al compared survivorship and 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, including aseptic loosening, instability, periprosthetic fracture, or 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
There are a large number of RCTs 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 have not shown that these differences in alignment lead to improved patient outcomes.

Summary of Evidence
For individuals who are undergoing ligament reconstruction, orthopedic surgery for trauma or fracture, 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 available studies to detect changes in function, studies that assess health outcomes in a larger number of subjects with longer follow-up would permit greater certainty on the impact of this technology. The evidence is insufficient to determine the effects of the procedure on health outcomes.

Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventative Service Task Force Recommendations
Not applicable.

Key Words:
Computer-assisted navigation (CAN), total hip arthroplasty (THA), total knee arthroplasty (TKA), anterior cruciate ligament (ACL), computer-assisted minimally invasive total knee arthroplasty, periacetabular osteotomy, surgical-navigation system, VERASENSE™ Knee System, iASSIST™ Knee

Approved by Governing Bodies:
Because CAN is a surgical navigation 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, the FDA does not require data documenting the intermediate or final health outcomes associated with computer-assisted surgery. (In contrast, robotic procedures, in which the actual surgery is robotically performed, are subject to the more rigorous requirement of the PMA process.)

A variety of surgical navigation procedures have been cleared for marketing by FDA through the 510(k) process with broad labeled indications. For example, The OEC FluoroTrak 9800 plus is marketed for locating anatomic structures anywhere on the human body.

Several navigation systems have received FDA clearance specifically for TKA. These include the PiGalileo™ Computer-Assisted Orthopedic Surgery System, PLUS Orthopedics; OrthoPilot® Navigation System, Braun; Navitrack® Navigation System, and ORTHO soft. 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 utilized to place surgical instruments during surgery utilizing anatomical landmarks and other data specifically obtained intra-operatively (e.g., ligament tension, limb alignment, etc). 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.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity

Current Coding:

CPT codes:

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 and MRI images (list separately in addition to code for primary procedure)
0396T	Intra-operative use of kinetic balance sensor for implant stability during knee replacement arthroplasty (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)

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Policy History:

Medical Policy Group, June 2005 **(2)**
Medical Policy Administration Committee, July 2005
Available for comment July 28-September 10, 2005
Medical Policy Group, June 2007 **(1)**
Medical Policy Group, February 2008
Medical Policy Group, February 2010 **(1):** Updated Key Points and References
Medical Policy Group, May 2011 **(1):** Updated Key Points and References
Medical Policy Group, July 2012 **(4):** Updated Key Points and References. Policy statement remained unchanged.
Medical Policy Panel, July 2013
Medical Policy Group, July 2013 **(3)**: Updated Key Points and References; no change in policy statement
Medical Policy Panel, July 2014
Medical Policy Group, July 2014 **(3)**: 2014 Updates to Description, Key Points & References; no change in policy statement
Medical Policy Panel, July 2015
Medical Policy Group, July 2015 (**2**): 2015 Updates to Description, Key Points, Key Words, and References; no change to policy statement.
Medical Policy Group, November 2015: 2016 Annual Coding update. Added CPT code 0396T
Medical Policy Group, December 2016 **(7):** Clarification to Policy Statement- added "including but not limited to." No change in policy intent.
Medical Policy Panel, January 2017
Medical Policy Group, January 2017 **(7):** Updates to Title, Description, Key Points & References. Clarification to Policy Statement- removed "musculoskeletal." No change in policy intent.
Medical Policy Panel, April 2018
Medical Policy Group, May 2018 (7): Updates to Key Points and Approved by Governing Bodies. No new literature to add. Previous Coding section deleted. No change in Policy Statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.