Computer-Assisted Surgical Navigation for Musculoskeletal Procedures (for New Mexico Only)

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➲ Instructions for Use

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Related Policies

- Surgery of the Hip (for New Mexico Only)
- Surgery of the Knee (for New Mexico Only)
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Application

This Medical Policy only applies to the state of New Mexico.

Coverage Rationale

Computer-assisted surgical navigation for musculoskeletal procedures of the pelvis and appendicular skeleton is unproven and not medically necessary due to insufficient evidence of efficacy.

The use of intra-operative kinetic balance sensor for implant stability during knee replacement arthroplasty is unproven and not medically necessary due to insufficient evidence of efficacy.

Definitions

Appendicular Skeleton System: Includes the bones of the shoulder girdle, the upper limbs, pelvic girdle, and the lower limbs (Anderson et al., 2022).

Musculoskeletal System: Provides form, support, stability, and movement to the body. It is made up of the bones of the skeleton, muscles, cartilage, tendons, ligaments, joints and other connective tissue that supports and binds tissues and organs together (NIH, 2023).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarifications:

- Intra-operative use of kinetic balance sensor for implant stability during knee replacement arthroplasty is considered incidental to the primary procedure being performed and is not eligible for separate reimbursement.
- The codes addressed within this policy are intended for navigational procedures for pelvic and appendicular musculoskeletal procedures; for cranial and spinal procedures, refer to CPT codes 61781, 61782 or 61783.

CPT Code	Description
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)
27599	Unlisted procedure, femur or knee (e.g., kinetic balance sensor)

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Description of Services

Computer-assisted navigation (CAN) in musculoskeletal 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 (knee and hip), and verification of intended implant placement. The goal of CAN in musculoskeletal procedures is to increase surgical accuracy and reduce the chance of malposition.

CAN may be image-based or non-image-based. Image-based devices use preoperative computed tomography (CT) magnetic resonance imaging (MRI) scans, ultrasounds, or operative fluoroscopy to direct implant positioning. Newer non-image-based devices are characterized by the fact that it does not require preoperative and postoperative images for planning and guiding surgery. Instead for these procedures, joint kinetic information and bone morphology information are used for planning and to devise guiding maps. For orthopedics, these systems were originally developed for total knee arthroplasty (TKA) and total hip arthroplasty (THA) applications. (Kubicek, et al., 2019).

CAN involves three steps described below:

- Data Acquisition: Data can be acquired via fluoroscopic, CT, or magnetic resonance imaging (MRI)-guided, or imageless systems. This data is then used for registration and tracking.
- Registration: Registration refers to the ability of relating data (i.e., x-rays, CT, MRI or patient's 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 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 (Swank and Lehnert, 2005).

A kinetic balance sensor is an electronic wireless sensor used in knee replacement surgery to align and balance the knee. The single-use sensors are used during knee replacement surgery to record measurable data pertaining to the limb alignment, joint rotation, and soft tissue balance through a full range of motion. This computer-assisted technology can help the surgeon in determining intercompartmental loading during range of motion evaluation to help anticipate soft tissue abnormalities affected by joint position. Wirelessly recorded data assists the surgeon with optimal component placement to properly balance and position the knee. It is thought to help reduce the number of revisions performed due to instability and loosening of implant components. (EncoderPro.com Expert).

Clinical Evidence

Hip/Pelvis

The evidence on the relative benefits of CAN with conventional or minimally invasive THA is inconsistent; quality randomized controlled trials (RCTs), and evidence for benefit of the technology on patient-centered outcome are lacking. The evidence is insufficient to determine the effects of the technology on net health outcomes.

In 2022 ECRI provided a report assessing evidence for the HipAlign a portable accelerometer-based navigation system intended to provide stereotaxic guidance in THA procedures. Another marketed version of this device is OrthoAlign Plus system. The focus of this report was on the HipAlign's safety and effectiveness, with comparison of HipAlign to conventional freehand THA techniques, and other THA guided alignment devices. The assessment analyzed one systematic review which included only three small studies one of which was a randomized controlled trial along with four nonrandomized comparison studies. Although the evidence suggests the HipAlign aids cup alignment during THA, ECRI found the studies were inconclusive providing very low-quality evidence and reporting on surrogate outcomes which could not determine improvement of patient-oriented outcomes compared to conventional THA techniques or other alignment devices.

Kunze et al. (2022) conducted a meta-analysis and systematic review of randomized controlled trials (RCTs) to determine whether differences in surgical times, adverse events (AEs) and implant positioning existed between manual, robotic-assisted, and computer navigation THA at a minimum of one year follow-up. A total of 12 RCTs that included 1,139 patients were analyzed in this study. Seven RCTs compared computer navigation and manual THA and five compared robotic-assisted THA with manual THA. Manual THA was associated with significantly less surgical time in comparison to CAN (mean difference: 23.3 minutes) with no difference in all cause complications (CAN: 1.7%, manual: 6.6%, and robotic-assisted; 16.2%) or revisions (CAN: 1.0%, manual: 1.7%, and robotic-assisted: 4.8%). In three studies positioning of acetabular implant with CAN had significantly higher percentage of safe placement (79% versus 52% $p = 0.02$). Even though CAN increased precision placement of the acetabular implant, the study concluded manual THA results in significantly shorter surgical times and a similar incidence of complications and revisions compared with robotic-assisted and computer-assisted THA.

Lass et al. (2020) conducted a two-year follow-up prospective randomized study (Lass et al. 2014 discussed below) to compare computer-assisted to manual implantation techniques in THA. The study analyzed if computer-assisted surgery can improve the clinical and functional results and reduce dislocation rate shortly after THA. Although a significant difference was found in mean postoperative acetabular component anteversion and in outliers regarding inclination and anteversion ($p < 0.05$) between CAN and the manual placed group, no significant difference regarding clinical outcome or revision rates at short-term or 2-year follow-up were found. Therefore, further long-term follow-up of patient groups is needed.

In a 2019 clinical evidence assessment product brief, ECRI reported their findings regarding the Intellijoint® Hip surgical navigation system. In summary, there is no comparative data available to determine how well the Intellijoint Hip system works to reduce complications and risk of revision surgery compared to conventional freehand techniques, or how it compares with other navigation systems. There were only two small single-arm studies available and both were at high risk of bias. High quality randomized controlled trials are needed and none were identified.

Snijders et al. (2017) conducted a systematic review and meta-analysis to assess the precision (variance) and accuracy (deviation from the target) from all available high-quality randomized control trials to date on imageless navigation (NAV) versus freehand implantation of THA. The aim of this study has been to compare the precision and accuracy of the anteversion and inclination of the acetabular cup position after NAV implantation and after freehand implantation of THA. Six out of seven studies concluded a statistically significant difference in precision in anteversion between the NAV group and the freehand group. Five out of seven studies concluded a statistically significant difference in precision in inclination. There is a significantly better accuracy for the NAV group than for the freehand group for anteversion ($p = 0.002$) and for inclination ($p = 0.01$). The authors concluded that this study showed that NAV placement is more precise and has an improved accuracy for anteversion and inclination than freehand placement of the acetabular cup. However, there is a lack of evidence to support an improved functional outcome and a reduction of complications and revisions.

In a cohort study by Aoude et al. (2016), the American College of Surgeons National Surgical Quality Improvement Program database was used to identify patients who underwent a primary, unilateral THA and TKA with or without computer-assisted surgery (CAS) technology from 2011 to 2013. Multivariate analysis was conducted to compare the postoperative complications in patients whose surgery involved the use of CAS with those using conventional techniques. The authors identified 103,855 patients who had THA and TKA in the database. The results also showed higher overall adverse events (AEs), minor events and requirements for blood transfusion in the conventional group when compared to CAS for THA. Superficial wound infections were shown to be higher in the CAS group undergoing THA. The authors concluded the use of CAS in THA reduced the number of minor AEs in the first 30 days postoperatively. However, CAS was associated with an increased number of reoperations and superficial infections. These findings are limited by the observational design of the study with possible bias and confounding by indication or other important unmeasured confounding factors.

Lass et al. (2014) conducted a prospective randomized study of two groups of 65 patients each. They compared the acetabular component position when using the imageless navigation system compared to the freehand conventional technique for cementless THA. The position of the component was determined postoperatively on computed tomographic scans of the pelvis. There was no significant difference for postoperative mean inclination ($p = 0.29$), but a significant difference for mean postoperative acetabular component anteversion ($p = 0.007$), for mean deviation of the postoperative anteversion from the target position of 15° ($p = 0.02$) and for the outliers regarding inclination ($p = 0.02$) and anteversion ($p < 0.05$) between the computer-assisted and the freehand-placement group. The authors concluded that their results demonstrated the importance of imageless navigation for the accurate positioning of the acetabular component. While this study appears to show improvement in some, but not all, components of accuracy, the findings are limited by lack of group comparison on patient-centered outcomes.

Reininga and colleagues (2013) conducted a randomized controlled trial (RCT) that investigated the effectiveness of a minimally invasive computer-navigated anterior approach for THA compared to a conventional posterolateral THA technique on the restoration of physical functioning during recovery following surgery. A total of 75 participants were included in the study; 35 underwent minimally invasive computer-navigated THA via the anterior approach, and 40 underwent THA using the conventional posterolateral approach. Gait analysis was performed preoperatively at intervals of 6 weeks, and three and six months using a body-fixed-sensor based gait analysis system. Cadence, walking speed, step length and frontal plane angular movements of the pelvis and thorax were evaluated. The same data were obtained from 30 healthy individuals. No between-group differences were noted in gait outcomes, the recovery of spatiotemporal parameters or in angular movements of the pelvis and thorax following either approach. The authors concluded that “no evidence was found for a faster recovery of gait following computer-navigated minimally invasive anterior approach for THA”.

Knee

The evidence suggests that the main difference found between TKA with and without CAN is increased surgical time with CAN. Few differences in clinical and functional outcomes were seen at up to 12 years post procedure. The evidence is inconclusive to determine the effects of the technology on overall health outcomes.

In 2021 ECRI provided a report assessing evidence for the KneeAlign a palm-sized CAN system intended to aid in calculating cutting block alignment relative to the mechanical axis for distal femur and proximal tibia resection cuts during knee arthroplasty. This report compared the clinical outcomes using KneeAlign with outcomes of conventional knee arthroplasty and other navigation techniques. Although the evidence suggests using KneeAlign improves implant alignment compared with conventional TKA, the studies were inconclusive with too few data on outcomes of interest and did not demonstrate whether KneeAlign improves knee function and patient-oriented outcomes compared with traditional methods for implant alignment or other navigation techniques.

Lee et al. (2020) conducted a meta-analysis to compare mid-to long-term clinical outcomes (such as knee scoring and functional results) and radiological outcomes (such as normal alignment of the limb axis or component) between computer navigated TKA and conventional TKA. The study analyzed seven randomized controlled trials where no significant difference was found in radiologic outcomes and clinical outcomes in the two techniques. It remains unclear which TKA technique yields better results in terms of mid-to long-term clinical and radiological outcomes.

Matar et. al (2020) conducted a systematic review and meta-analysis of 403 randomized controlled trials with a total of 47,675 patients in TKA summarizing the available high-quality evidence of healthcare interventions. The studies were classified according to intervention groups; surgical approach, tourniquet use, minimally invasive, patient specific instrumentation, knee design, fixation, mobile bearing, navigation, polyethylene, technique, patella resurfacing, drain, closure and other. The largest subgroup intervention was navigation with 50 RCTs and 5,936 patients. The analyzed evidence of 40 of the 50 navigation-related RCTs reported no significant differences in outcomes; 35 RCTs compared navigation and computer-assisted technique with conventional TKA and 5 RCTs compared different aspects of navigation surgery. Ten RCTs reported significant findings however those findings were mainly with improved radiological outcomes with no difference in clinical outcomes (9 RCTs). Only one RCT reported improved clinical outcomes in favor of navigation. The overall results concluded a standard conventional TKA with surgical approach familiar to the surgeon using standard well-established components, with or without a tourniquet and without surgical drain leads to satisfactory long-term outcomes. [Authors Cip 2018, Song 2016, and Harvie 2012, previously cited in this policy, are included in the Matar (2020) systematic review and meta-analysis].

A Hayes Comparative Effectiveness Review (2019, updated 2022) on image-based computer-aided navigation (CAN) for total knee arthroplasty performed a comprehensive search using PubMed and Embase for studies reported from 2012 through March 2019. The evidence was comprised of:

- One RCT comparing fluoroscopic-based CAN (FI-CAN) with conventional (CONV) in patients undergoing total Knee arthroplasty (TKA).
- Two RCTs and three nonrandomized prospective studies comparing computed tomography (CT)-based CAN (CT-CAN) with CONV TKA.
- Two RCTs and two nonrandomized prospective studies comparing CT-CAN and imageless CAN.

The review found that the key disadvantages of image-based CAN relative to imageless CAN include greater expense, more time for preoperative planning, longer duration of surgery, and increased patient radiation exposure. CT image based CAN for use in TKA may confer some alignment advantages with unclear clinical benefit over conventional navigation; however, evidence indicates no advantage with CT-based CAN over imageless CAN on alignment and function outcome measures. Fluoroscopic CAN is addressed by an inadequate quantity of evidence to inform conclusions. Evidence on complications is insufficiently reported to enable critical interpretation of its quality; a minority of included studies reported safety outcomes and it is unclear from published accounts whether no events occurred or if not reported.

Panjwani et. al (2019) conducted a systematic review and meta-analysis comparing functional outcomes for TKA of CAN systems versus conventional technique with a minimum two-year follow-up. The review included a total of 18 studies with 3,060 knees of which 1,538 underwent TKA with CAS and 1,522 underwent conventional TKA. The evidence suggests restoration of mechanical axis during TKA has been associated with better outcomes however, the evidence with regards to whether CAS-TKA improves patient function and/or longevity of TKA is unclear. The study concluded that there is limited evidence that CAS-TKA improves functional outcomes at 5- to 8-year follow-up. More prospective studies with larger sample size and longer-term follow-up are required to support the trend toward better functional outcomes with CAS.

ECRI (2018, updated 2020) assessed 4 non-randomized comparison studies that reported the results on 1,491 patients regarding the use of the VeraSense Knee System for soft tissue balancing during TKA The evidence is inconclusive due to very low-quality comparative data. Ongoing clinical trials reporting knee function and patient satisfaction at up to one year follow up may address evidence gaps.

In the same cohort study by Aoude et al. (2016) mentioned earlier for THA, the American College of Surgeons National Surgical Quality Improvement Program database was used to identify patients who underwent a primary, unilateral TKA with or without CAS technology from 2011 to 2013. Multivariate analysis was conducted to compare the postoperative complications in patients whose surgery involved the use of CAS with those using conventional techniques. The authors identified 103,855 patients who had THA and TKA in the database. The rate of reoperation was higher in the CAS group for TKA. The authors concluded the use of CAS in TKA reduced the number of minor AEs in the first 30 days postoperatively. However, CAS was associated with an increased number of reoperations and superficial infections. These findings are limited by the observational design of the study with possible bias and confounding by indication or other important unmeasured confounding factors.

Rebal and colleagues (2014) conducted a meta-analysis of level I RCTs comparing TKA using imageless computer navigation to conventional instrumentation. Based on radiographic and functional outcomes analysis, TKA performed with computer navigation was more likely to be within 3° of ideal mechanical alignment (87.1% vs. 73.7%). Navigated TKAs had a higher increase in Knee Society Score at three month follow-up (68.5 vs. 58.1) and at 12-32 month follow-up (53.1 vs. 45.8). Although the authors found that computer navigation in TKA provides more accurate alignment and superior functional outcomes at short-term follow-up, the impact on long term functional outcomes has yet to be firmly demonstrated.

Yaffe and colleagues (2013) reported the results of a study that explored whether differences in clinical, functional, or radiographic outcomes existed at 5-year follow-up between subjects who underwent computer-assisted or manual TKA. At 5 years, 63 participants (34 from the manual group and 29 from the computer-assisted group) were evaluated. No statistically significant differences were found in the Knee Society knee score, function score, range of motion, pain score or UCLA activity score between the two groups.

In 2011, Barrett and colleagues (included in the meta-analysis by Rebal, 2014 described above), in a multicenter, prospectively randomized trial, compared the radiographic alignment of imageless CAS with conventional instrumentation in individuals undergoing TKA. A total of 208 subjects were enrolled in the study. The preoperative surgical plan was compared to postoperative 2-dimensional radiographic alignment measured by a blinded reviewer. The authors found that the use of CAS did not offer a clinically meaningful improvement in postoperative alignment, clinical, functional, or safety outcomes compared with conventional TKA.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

The AAOS Clinical Practice Guidelines for surgical management of osteoarthritis of the knee states that there is “strong evidence” to support not using intraoperative navigation in TKA because there is no difference in outcomes or complications (2016, updated 2022).

Other Pelvis and Appendicular Skeletal Indications

Computer-assisted musculoskeletal navigation has been primarily investigated as an adjunct to surgery of the appendicular skeletal system. Most of the research has focused on its use in the knee and hip. There is only very preliminary literature regarding its use in the upper extremity (shoulder and elbow) and axial skeleton (spine). Evidence suggests that, although CAN for trauma, fractures, or other pelvis and appendicular skeleton conditions may improve the precision of bone cutting and alignment of prosthetic devices, the impact on improved clinical outcomes is unclear. Additional controlled studies that measure health outcomes are needed to evaluate this technology for these indications. Further analysis is needed to evaluate the impact of this approach on patient outcomes.

Pan et al. (2022) conducted a small RCT for patients (10 in the navigation group and 10 in the traditional group) admitted for arthroscopic capsulolabral repair surgery. Penetration rates were compared between the groups divided into four zones of the glenoid. The penetration rate in zone 3 the most inferior region of the glenoid, showed 40.9% in the traditional group and 15.7% in the navigation group ($p = 0.077$) demonstrating a trend toward improved accuracy of anchor placement with the aid of the navigation system; however, this was not statistically significant. In addition, there was no difference in American Shoulder and Elbow Surgeons Shoulder Scores before and six months after surgery. Although this study showed a trend toward decreased penetration rate in O-arm navigated capsulolabral repair surgeries and decreased risk of implant misplacement, the difference was not statistically significant possibly due to small sample size. In conclusion further large-scale studies are needed to confirm the possible benefit of navigation systems.

Ansari et al. (2021) conducted a retrospective cohort study analyzing data from 2011 to 2018, to determine the effect of spinal CAN on short-term clinical outcomes following posterior cervical fusion. A total of 12,578 patients were identified and separated into cohorts (689 CAN and 11,889 were non-CAN) rates of 30-day unplanned readmission, reoperation, and other complications were evaluated. In addition, a separate subgroup comparison of patients was established who were undergoing C1-C2 or occiput C2 fusion. After adjusting for baseline differences there was no significant distinction in the 30-day complication, readmission, or revision rates; however, patients receiving CAN experienced longer operations and had higher total relative value units associated with care. At the occipitocervical junction there were more hardware revisions, but this effect did not reach statistical significance. In conclusion, the use of CAN does not seem to affect 30-day postoperative complications, readmissions or need for revision surgery. The use of CAN is more common in procedures where anatomy may be variable and navigation may be more of assistance, given the lack of differences in complication rates despite increased operation length. The overall opinion of the authors states surgeons should embrace CAN at their own discretion in cases expected to be of high operative complexity.

Kinetic Balance Sensor

Review of the peer-reviewed medical literature shows evidence for the use of intra-operative kinetic balance sensor for implant stability during TKA is lacking. Further evidence with high-quality RCTs is needed to determine the safety, efficacy, and impact on clinical outcomes.

In 2022 Sun and colleagues conducted a meta-analysis to evaluate if sensor-guided balancing improves postoperative clinical outcomes compared to conventional gap balancing technique. Nine studies (randomized and non-randomized controlled trials) were assessed identifying 2,147 patients. When compared with manual gap balancing, sensor-guided gap balancing resulted in less manipulation under anesthesia ($p = 0.02$), however, higher rates of intraoperative procedures ($p = 0.0003$). There was no statistically significant improvement in terms of function, operative time, mechanical axis, and rate of reoperation when contrasting the two groups. In conclusion, when comparing conventional manual gap balancing techniques more sensor-guided gap balancing procedures are being performed and resulted in reduction in the rate of manipulation under anesthesia but more extensive, high-quality RCTs are required to verify these findings further.

Wood et al. (2021) conducted a prospective double-blind randomized controlled trial of 152 patients (76 sensor-guided experimental and 76 control cases) electing primary TKA to determine a difference in TKA soft tissue balance. This study focused on the standard gap balancing (tensiometer) approach versus using a sensor-guided device. The sensor-guided experimental group had adjustments made to achieve a balanced knee within 15 pounds of intercompartmental pressure variance and secondary outcomes differentiating clinical outcome scores at 6 months and 1 year postoperative. Within the control group, 36% of knees were unbalanced based on average coronal plan intercompartmental difference > 15 pounds, compared to only 5.3% within the experimental group (p < .001). In addition, there were no significant differences in 1-year postoperative flexion and patient satisfaction at one year was comparable with 81% controls and experimental cases (p = .992). In conclusion the use of sensor-guided knee balancer device provided additional feedback during TKA however, it was unable to demonstrate improved clinical outcomes or patient satisfaction compared to conventional gap balancing technique.

MacDessi et al. conducted a 2020 RCT comparing patients undergoing TKA assigned to kinematic alignment (KA) versus mechanical alignment (MA) to determine whether KA protocols resulted in better quantitative knee balance. According to the authors, the results of this study provide persuasive evidence that restoration of the patient's constitutional alignment within a restrictive kinematic safe zone significantly improved knee balance, reduced knee balancing procedures, and may more closely restore native soft-tissue tension when compared with MA. Despite these findings, the study failed to show group difference in functional patient-centered outcomes. Further high-quality randomized trials with long-term follow-up to evaluate efficacy, safety, and subsequent revision risk are needed to confirm the validity and efficacy of this approach, as well as its clinical significance on relevant outcomes.

Cho et al. (2018) observed significant decrease in both medial and lateral compartments pressure after TKA in a case series of 84 patients who underwent TKA using the OrthoSensor. Using the OrthoSensor, patients could obtain 94% quantified balanced knee, consequently. Between the techniques, measured resection TKA showed less balanced knee in the initial pressure measurement and also required more additional procedures compared to modified gap balancing TKA. The authors suggested that regardless of TKA surgical methods, additional procedures could be needed for adequate "patient-specific" ligament balancing. Furthermore, with the consistent data of the OrthoSensor acquired during appropriate ligament balancing, a surgeon could eventually reduce the complications associated with soft tissue imbalance in the future. The findings are limited by lack of comparison group, lack of functional outcomes, and short follow-up.

Gustke et al. (2017) conducted a multicenter case series examining intraoperative data of 129 patients who had TKA surgery with sensor assistance. The study found that loading across the joint decreased, overall and became more symmetrical after releases were performed. On average, between two and three corrections were made (up to eight) in order to achieve ligament balance. The authors concluded that objective data from sensor output may assist surgeons in decreasing loading variability and, thereby, decreasing ligament imbalance and its associated complications. Of note, one or more authors on this study reported a potential conflict of interest with this work. Additionally, the findings are limited by lack of comparison group and limited duration of follow-up.

Gustke et al. (2014) conducted a multicenter case series of intra-operative kinetic balance sensors with 176 participants undergoing TKA performed with the use of the VERASENSE™ Knee System. The authors found that participants with balanced joints were more likely to have favorable clinical outcomes. While power analyses did confirm that comparisons could be reasonably made, an equal proportion of patients in each group would have been more favorable. Controlled trials with longer follow-up are needed to demonstrate that use of intra-operative kinetic balance sensors for implant stability during knee replacement arthroplasty results in improved clinical outcomes. Study limitations included the lack of a control group and the number of unbalanced patients which was much smaller than balanced patients.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Surgical navigation systems require U.S. Food and Drug Administration (FDA) clearance, but generally are subject only to 510(k) clearance since CAS is considered analogous to a surgical information system in which the surgeon is only acting on the information that is provided by the navigation system. As such, the FDA does not require data documenting the intermediate or final health outcomes associated with CAS.

A variety of CAN devices for orthopedic surgery have been approved by the FDA through the 510(k) process, including but not limited to:

- CTC TCAT®-TPLAN® Surgical System
- Digimatch Orthodoc Robodoc Encore Surgical System
- ExactechGPS
- iASSIST Knee System
- Intellijoint® Navigation System (Hip and Knee)
- JointPoint
- KneeAlign

- NuVasive Next Generation NVM5 System
- NuVasive Pulse System
- OrthAlign Plus System
- Stryker Navigation System with Spinemap Go Software
- Stryker OrthoMap Versatile Hip System
- Verasense for Zimmer Biomet Persona
- Verasense Knee System
- Vital Navigation System

For additional information on approved FDA surgical navigations systems, search the following site by device name: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. (Accessed June 21, 2023)

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Policy History/Revision Information

Date	Summary of Changes
07/01/2024	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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