Computer-Assisted Surgical Navigation for Musculoskeletal Procedures (for Ohio Only)

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Instructions for Use

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Related Policies

- Articular Cartilage Defect Repairs (for Ohio Only)
- Surgery of the Hip (for Ohio Only)
- Surgery of the Knee (for Ohio Only)
- Surgery of the Shoulder (for Ohio Only)

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

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.

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.

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)

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 3 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)

Hip/Pelvis

The evidence on the relative benefits of CAN with conventional or minimally invasive total hip arthroplasty is inconsistent; quality randomized controlled trials, 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 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 2 small single-arm studies available and both were at high risk of bias. High quality randomized controlled trials are needed and none were identified.

Snijder 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 total hip arthroplasty (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 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 the 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, included in the Snijder systematic review above)) 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 total hip arthroplasty. 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 total hip arthroplasty (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 3 and 6 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”.

A meta-analysis by Gandhi et al. (2009) found 3 relevant studies documenting the efficacy of computer assisted hip surgery; the meta-analysis suggested a benefit of computer assisted surgery on the rate of outliers for of acetabular cups outside the desired alignment range. The authors concluded that while computer navigation appears promising for alignment of the acetabular cup, further studies are needed to evaluate the impact of this on clinical outcomes, survival and quality of life (QOL).

Knee

The evidence suggest that the main difference found between total knee arthroscopy (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 conflicting to determine the effects of the technology on overall health outcomes.

A 2020 update to a 2018 clinical evidence assessment, ECRI 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 total knee arthroplasty. 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.

A 2019 Hayes Comparative Effectiveness Review 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 comprised:

- One RCT comparing fluoroscopic-based CAN (Fl-CAN) with conventional (CONV) in patients undergoing total Knee arthroplasty (TKA)
- Two RCTs and 3 nonrandomized prospective studies comparing computed tomography (CT)-based CAN (CT-CAN) with CONV TKA.
- Two RCTs and 2 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.

In a prospective randomized trial, Cip et al. (2017) compared 100 conventional total knee arthroplasty (TKA) with 100 computer-assisted TKAs after a mean follow-up of 12 years postoperatively. A long-leg weight-bearing X-ray was performed for measuring mechanical axis of the limb, lateral distal femoral angle, and medial proximal tibial angle. Tibial slope, patella alpha angle, and radiolucent lines were also observed. Clinical investigation included evaluation of 4 different scores: Insall Knee Score, Western Ontario and MacMaster University Index score, Hospital for Special Surgery Knee Score, and visual analog scale. Based on a follow-up rate of at least 75%, no differences were found in terms of long-term survival, implantation accuracy, clinical outcome or score results between the two study groups.

In a 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 THA and 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.

Song and colleagues (2016) conducted a prospective randomized study comparing navigation-assisted TKA and conventional TKA reported the clinical and radiological outcomes at a follow-up of 9 years. The purpose of this study was to compare the

clinical and radiological outcomes for patients who underwent navigation-assisted TKA or conventional TKA after long-term follow-up. A total of 80 patients (88 knees) were available for physical and radiological examination 9 years after TKA. Clinical outcomes were evaluated using HSS, WOMAC, and KS function and pain scores. And radiological outcomes of the component loosening and its survivorship during 9-year follow-up were also evaluated. The results showed no significant differences in the field of clinical outcomes between the two groups. In terms of radiological outcomes, the navigation group had fewer alignment outliers (7.3 vs 20 %, p = 0.006). Although the clinical outcomes showed no differences between the two groups, the survival rate was slightly better in the navigation group than in the conventional group without statistical significance (best-case scenario 100 vs 95.3 %, n.s., worst-case scenario 95.6 vs 88.4 %, n.s.). The authors concluded that CAN TKA produced better alignment outcomes and better survival rates than conventional instruments although some of the differences were not statistically significant. Strengths of the study included the excellent follow up rate (90%) over a 9-year period. However, the clinical significance of the misalignment benefit remains to be proven, considering that the study failed to demonstrate group differences in patient-centered outcomes, such as range of motion, pain, and functional status.

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 3-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.

Yaffee 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 2 groups.

Harvie and colleagues (2012, reviewed in the systematic review by Rebal described above) reported on 71 subjects who were randomly allocated to undergo either computer-navigated or conventional TKA. A statistically significant improvement in alignment was seen in the computer-navigated group. Five-year functional outcome was assessed using the Knee Society, Short Form-36, Western Ontario and McMaster Universities Osteoarthritis Index, and a patient satisfaction score. At 5 years, 46 of the study participants were available for assessment (24 navigated and 22 conventional knees). None of the participants had undergone revision. No statistically significant difference was observed in any component of any measure of outcome between the groups. Longitudinal data showed function to be well maintained with no difference in functional score between 2 and 5 years in either group. The authors concluded that despite achieving better alignment, the functional outcome with computer-navigated knee arthroplasty appears to be no different at 5 years than those seen using a conventional jig-based technique.

In 2011, Barrett and colleagues (reviewed in the systematic review by Rebal 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.

Cheng et al. (2010) conducted a meta-analysis of 40 studies (29 quasi-randomized and RCTs and 11 prospective studies) and found that imageless CAN systems improve lower limb axis and component orientation in the coronal and sagittal planes, but not the rotational alignment in TKA. Further multiple-center clinical trials with long-term follow-up are needed to determine differences in the clinical and functional outcomes of knee arthroplasties performed using computer-assisted techniques.

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 (2015).

Other Pelvis and Appendicular Skeleton Musculoskeletal 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 computer-aided navigation (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.

Kinetic Balance Sensor

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

MacDessi et al. conducted a 2019 RCT, comparing patients undergoing total knee arthroplasty 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. (2018) The findings are limited by lack of comparison group, lack of functional outcomes, and short follow-up.

Gutke 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 2 and 3 corrections were made (up to 8) 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 computer-assisted surgery 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 computer-assisted surgery.

A variety of computer-assisted navigation 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
- NuVasive Next Generation NVM5 System
- NuVasive Pulse 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 December 8, 2022)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2023	**Applicable Codes** • Added CPT code 20985 **Supporting Information** • Archived previous policy version CS167OH.A – P

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) 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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