

COMPUTER-ASSISTED SURGICAL NAVIGATION FOR MUSCULOSKELETAL PROCEDURES

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[Instructions for Use](#) ⓘ

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Related Commercial Policies

- [Autologous Chondrocyte Transplantation in the Knee](#)
- [Hip Resurfacing and Replacement Surgery \(Arthroplasty\)](#)
- [Knee Replacement Surgery \(Arthroplasty\), Total and Partial](#)
- [Shoulder Replacement Surgery \(Arthroplasty\)](#)

Community Plan Policy

- [Computer-Assisted Surgical Navigation for Musculoskeletal Procedures](#)

COVERAGE RATIONALE

Computer-assisted surgical navigation for musculoskeletal procedures 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.

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 the member specific benefit plan document 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 Coverage Determination Guidelines may apply.

Coding Clarification: 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.

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)
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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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) scans and operative fluoroscopy to direct implant positioning. Newer non-image based devices use information obtained in the operating room, typically with infrared probes.

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 images (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 "fiducial 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).

CLINICAL EVIDENCE

Hip/Pelvis

A meta-analysis by Gandhi et al. (2009) found 3 relevant studies documenting the efficacy of computer assisted hip surgery; however all had small sample sizes. The authors found 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).

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 differences were noted in the recovery of spatiotemporal parameters or in angular movements of the pelvis and thorax following either approach. The authors found that while there was an improvement in gait after surgery, small differences in several spatiotemporal parameters and angular movements of the trunk remained at 6 months postoperatively between both the participants and the healthy subjects.

Knee

Aoude et al. (2016) reported computer-assisted surgery (CAS) has gained popularity in orthopedics for both total knee arthroplasty (TKA) and THA in the past decades. The American College of Surgeons National Surgical Quality Improvement Program database was used to identify patients who underwent a primary, unilateral THA and TKA 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 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 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. The clinical benefits and disadvantages of CAS should be considered when determining the potential benefit-cost ratio of this technology.

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) 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, 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.

A meta analysis by Bauwens et al. (2007), of 33 studies (11 randomized trials) involving 3423 patients were reviewed comparing navigated and conventional knee arthroplasty and concluded that the navigated knee replacement provided few advantages over conventional surgery based on radiographic evidence; therefore, its clinical benefits are unclear and remain to be defined on a larger scale. Similar findings were confirmed by Brin et al. (2011) in a meta-analysis of 23 papers. The authors found that while imageless navigation improves component orientation and postoperative limb alignment, further studies are needed to evaluate the clinical benefits.

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.

A study by Hasegawa et al. (2010) compared standard approach (jig-based) TKA with CAN in 100 equally divided patients. The authors found no significant differences between the procedures in the frontal and sagittal planes as well as rotational alignment of the femoral or tibial components.

A 2007 Blue Cross Blue Shield (BCBS) Association TEC Assessment evaluated CAN for TKA. Nine studies from 7 RCTs were reviewed. Selection criteria 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. Based on the deficiencies in the available evidence (e.g., potential for bias in observational studies, lack of long-term follow-up in the RCTs), the TEC reviewers concluded that it was not possible to determine whether the degree of improvement in alignment reported in the RCTs led to meaningful improvements in clinically relevant outcomes such as pain, function, or revision surgery.

Professional Societies

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).

American Association of Hip and Knee Surgeons (AAHKS)

In their 2008 Position Statement, the AAHKS states that longer and more comprehensive follow-up computer assisted orthopedic surgery (CAOS) studies are needed to better understand the indications, limitations and complications of this surgical technology. Future studies will also determine if the short term improvements reported from CAOS can

increase joint implant longevity and improve overall outcomes for patients undergoing total hip and knee replacement surgery.

Other Musculoskeletal Indications

Based on review of the literature, there is limited evidence on the use of CAN for trauma, fractures, or other musculoskeletal conditions. Additional controlled studies that measure health outcomes are needed to evaluate this technology for these indications.

Kinetic Balance Sensor

A 2018 Hayes report examined the Verasense (OrthoSensor, Inc.) for use during TKA. The literature search identified 3 eligible studies (n=54 to 158 patients) that evaluated the effect of Verasense-assisted-TKA (VSA-TKA) on clinical outcomes. Overall, a very-low-quality body of evidence does not allow for definitive conclusions to be drawn regarding the efficacy, comparative effectiveness, or safety of VSA-TKA. Currently, there is no evidence to support the use of Verasense over other soft-tissue balancing procedures, such as manual balancing. All eligible studies reviewed in this health technology assessment evaluated the use of the sensor-embedded device after conventional manual alignment; therefore, no conclusion can be drawn regarding the efficacy of VSA-TKA.

A multicenter observational study of intra-operative kinetic balance sensors was conducted by Gustke et al. (2014). Study limitations included the lack of a control group and the number of unbalanced patients was much smaller than balanced patients. 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.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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.

The Verasense Knee System received 510(k) clearance on November 8, 2013. Additional information is available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K131767>. (Accessed July 10, 2019)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for computer-assisted surgical navigation for orthopedic procedures. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for [Noncovered Services](#) and [Services That Are Not Reasonable and Necessary](#).

Medicare does not have an NCD for the use of intra-operative kinetic balance sensor for implant stability during knee replacement arthroplasty procedures. LCDs exist, see the LCDs for [Non-Covered Category III CPT Codes](#), [Noncovered Services](#) and [Services That Are Not Reasonable and Necessary](#). (Accessed April 10, 2019)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
10/01/2019	<p>Template Update</p> <ul style="list-style-type: none"> Reformatted policy; content previously located in the Medical Policy titled <i>Omnibus Codes</i> <p>Applicable Codes</p> <ul style="list-style-type: none"> Added notation to indicate 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 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services, Clinical Evidence, FDA, CMS, and References</i> sections to reflect the most current information Archived previous policy version 2019T0535ZZ

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.