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

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Instructions for Use

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Related Policies

- Surgery of the Hip (for Ohio Only)
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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 an intra-operative sensor for implant stability during knee replacement arthroplasty and for improved knee function post-operatively 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 a 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, see CPT code 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., sensor)

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 sensor is an electronic device that measures physical properties such as temperature, pressure, distance, speed, torque, acceleration, force, flow, etc., and sends the information to an electronic processor. Smart sensor assisted can be used intraoperatively to provide objective assessment of ligament and soft tissue balancing whilst maintaining the sagittal and coronal alignment to achieve desired kinematic targets following total knee arthroplasty. It can also provide post-implantation data to monitor implant performance in natural conditions and patient's clinical recovery during rehabilitation. The ability of the sensors to measure multifarious data on patient's biological activities allows sensor technology to be used in the management of patient care (Iyengar et al., 2021).

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 1139 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.

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.

Sheridan et al. (2023) conducted a systematic review and meta-analysis to compare radiographic, clinical and functional outcomes between conventional TKA (C-TKA) and navigated computer-assisted methods (N-TKA). Seventeen eligible prospective RCTs were included in the meta-analysis. There was a cumulative total of 2201 TKAs (1063 in the conventional group and 1138 in the navigated group) included in the data extraction. Radiographic outcomes included postoperative coronal, sagittal and axial component alignment. Clinical outcomes included all-cause revision and aseptic revision.

Functional outcomes were analyzed when reported. The results demonstrated there was no difference in short-term clinical survivorship (all-cause, p = 0.649; aseptic, p = 0.79) or in functional outcomes reported between the N-TKA and C-TKA groups. There was a clinically significant reduction in the mean operative time in the conventional group relative to the navigated group. The mean conventional operative time was 87 min (σ = 16.6, 95% CI 76.4-98.8) compared to 97.6 min (σ = 16.9, 95% CI 86.2-109.1) in the navigated group (p = 0.17). Radiological outcomes showed normal coronal mechanical alignment of the tibial (p < 0.001) and femoral (p = 0.001) components were achieved more frequently with N-TKA. Normal sagittal mechanical alignment of the tibial component was achieved significantly more with N-TKA (p < 0.010). The authors concluded although navigated TKA achieves superior radiographic alignment, operative times are longer and functional outcomes are similar. Future prospective studies are required due to limited short-term follow-up on clinical 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 1522 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.

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.

TKA Sensors

The evaluation of the peer reviewed medical literature for the use of intra-operative sensor for implant stability during TKA and for improved knee function post-operatively shows evidence is lacking. Further high-quality RCTs is needed to determine the safety, efficacy, and impact on clinical outcomes.

Feng et al. (2023) conducted a systematic review aimed at analyzing the application of gait analysis in combination with wearable sensor technologies in post-TKA rehabilitation. The study included 25 articles (823 patients) receiving multiple techniques of TKA with gait evaluation from one week to five years post-operatively. Follow-up time points began at six weeks, three months, six months and one year, however few studies lasted for more than one year. The results showed inconsistencies in patient characteristics, sensor data and protocols with varied methodologies. Gait analysis using wearable sensors and patient-reported outcome measures (PROMs) showed differences in controlled environments, daily life, and when comparing different surgeries. The authors concluded wearable sensors can be used to monitor post-TKA gait function in unsupervised mode and on remote basis, providing additional clinical measurement methods and diagnostic approaches. However, more cohort longitudinal studies are warranted to further confirm the benefits of this remote technology in clinical practice. The limitations of the articles included in this systematic review are small sample size, varied methodologies, and limited parameters for measurement accuracy.

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 2147 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 19, 2024)

References

American Academy of Orthopaedic Surgeons (AAOS). Surgical management of osteoarthritis of the knee. Evidence-Based Clinical Practice Guideline. December 2022. Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/surgical-management-knee/smoak2cpg.pdf. Accessed June 19, 2024.

American Academy of Orthopaedic Surgeons (AAOS). Surgical management of osteoarthritis of the knee. Evidence-Based Clinical Practice Guideline. December 2016. Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/surgical-management-knee/smoak-cpg_4.22.2016.pdf. Accessed June19, 2024.

Anderson BW, Ekblad J, Bordoni B. Anatomy, Appendicular Skeleton. 2022 Jul 25. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–. PMID: 30571018.

Ansari D, Chiu RG, Kumar M, et al. Assessing the clinical safety profile of computer-assisted navigation for posterior cervical fusion; A propensity-matched analysis of 30-day outcomes. World Neurosurg. 2021;150:e530-e538.

Aoude AA, Aldebeyan SA, Nooh A, et al. Thirty-day complications of conventional and computer-assisted total knee and total hip arthroplasty: Analysis of 103,855 patients in the American College of Surgeons national surgical quality improvement program database. J Arthroplasty. 2016 Aug;31(8):1674-9.

Beyer F, Pape A, Lützner C, et al. Similar outcomes in computer-assisted and conventional total knee arthroplasty: ten-year results of a prospective randomized study. BMC Musculoskelet Disord. 2021 Aug 18;22(1):707.

Cheng T, Zhang G, Zhang X. Imageless navigation system does not improve component rotational alignment in total knee arthroplasty. J Surg Res. October, 2010.

Cho KJ, Seon JK, Jang WY, et. al. Objective quantification of ligament balancing using VERASENSE in measured resection and modified gap balance total knee arthroplasty. BMC Musculoskelet Disord. 2018;19(1):266.

Cip J, Obwegeser F, Benesch T, et al. Twelve-year follow-up of navigated computer-assisted versus conventional total knee arthroplasty: A prospective randomized comparative trial. J Arthroplasty. 2018 May;33(5):1404-1411.

ECRI. HipAlign (OrthAlign, Inc.) for total hip arthroplasty. Plymouth Meeting (PA): ECRI; 2022 Apr. (Clinical Evidence Assessment).

ECRI. Intellijoint Hip (Intellijoint Surgical, Inc.) for intraoperative navigation during hip arthroplasty.: December 2019. (Clinical Evidence Assessment).

ECRI. KneeAlign System (OrthAlign, Inc.) for guiding knee arthroplasty. Plymouth Meeting (PA): ECRI; 2021 Oct. (Clinical Evidence Assessment).

ECRI. VeraSense Knee System (OrthoSensor, Inc.) for sensor-assisted total knee arthroplasty. Plymouth Meeting (PA): ECRI; 2020 Oct 01. (Clinical Evidence Assessment).

Feng Y, Liu Y, Fang Y, et al. Advances in the application of wearable sensors for gait analysis after total knee arthroplasty: a systematic review. Arthroplasty. 2023 Oct 2;5(1):49.

Gandhi R, Marchie A, Farrokhyar F, et al. Computer navigation in total hip replacement: a meta-analysis. Int Orthop. 2009 Jun;33(3):593-7.

Gustke KA, Golladay GJ, Roche MW, et al. A new method for defining balance: promising short-term clinical outcomes of sensor-guided TKA. J Arthroplasty. 2014 May;29(5):955-60.

Gustke KA, Golladay GJ, Roche MW, et al. A targeted approach to ligament balancing using kinetic sensors. J Arthroplasty. 2017;32(7):2127-2132.

Harvie P, Sloan K, Beaver RJ. Computer navigation vs conventional total knee arthroplasty: five-year functional results of a prospective randomized trial. J Arthroplasty. 2012; 27(5):667-672.

Hayes, Inc. Comparative Effectiveness Review. Comparative effectiveness review of image-based computer-aided navigation for total knee arthroplasty. Lansdale, PA. March 29, 2019. Annual Review March15, 2022.

Iyengar KP, Gowers BTV, Jain VK, et al. Smart sensor implant technology in total knee arthroplasty. J Clin Orthop Trauma. 2021 Sep 22;22:101605.

Kubicek J, Tomanec F, Cemy M, et al. Recent Trends, Technical concepts and components of computer-assisted orthopedic surgery systems: A comprehensive review. November 2019;19(23):5199.

Kunze KN, Bovonratwet P, Polce EM, et al. Comparison of surgical time, short-term adverse events, and implant placement accuracy between manual, robotic-assisted, and computer-navigated total hip arthroplasty: A network meta-analysis of randomized controlled trials. J Am Acad Orthop Surg Glob Res Rev. 2022 Apr 1;6(4).

Lass R, Olischar B, Kubista B, et al. Total hip arthroplasty using imageless computer-assisted navigation-2-year follow-up of a prospective randomized study. J Clin Med. 2020 May 27;9(6):1620.

Lee DY, Park YJ, Hwang SC, et al. No differences in mid- to long-term outcomes of computer-assisted navigation versus conventional total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2020 Oct;28(10):3183-3192.

MacDessi SJ, Griffiths-Jones W, Chen DB, et al. Restoring the constitutional alignment with a restrictive kinematic protocol improves quantitative soft-tissue balance in total knee arthroplasty: a randomized controlled trial. Bone Joint J. 2020;102-B(1):117-124.

Matar HE, Platt SR, Gollish JD, et al. Overview of randomized controlled trials in total knee arthroplasty (47,675 Patients): What have we learnt? J Arthroplasty. 2020 Jun;35(6):1729-1736.e1.

National Institutes of Health (NIH). National Institute of Arthritis and Musculoskeletal and Skin Diseases. Muscle and bone diseases. February 2023. Accessed July 11, 2023.

Ohio Administrative Code/5160/Chapter 5160-1-01. Medicaid medical necessity: definitions and principles. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-1-01. Accessed August 21, 2024.

Pan HK, Liu CW, Pan RY. Comparison of suture anchor penetration rate between navigation-assisted and traditional shoulder arthroscopic capsulolabral repair. PLoS One. 2022 May 5;17(5):e0267943.

Panjwani TR, Mullaji A, Doshi K, et al. Comparison of functional outcomes of computer-assisted vs conventional total knee arthroplasty: A systematic review and meta-analysis of high-quality, prospective studies. J Arthroplasty. 2019 Mar;34(3):586-593.

Sheridan GA, Abdelmalek M, Howard LC, et al. Navigated versus conventional total knee arthroplasty: A systematic review and meta-analysis of prospective randomized controlled trials. J Orthop. 2023 Dec 6;50:99-110.

Snijders T, van Gaalen SM, de Gast A. Precision and accuracy of imageless navigation versus freehand implantation of total hip arthroplasty: A systematic review and meta-analysis. Int J Med Robot. 2017 Dec;13(4).

Song EK, Agrawal PR, Kim SK, et al. A randomized controlled clinical and radiological trial about outcomes of navigation-assisted TKA compared to conventional TKA: long-term follow-up. Knee Surg Sports Traumatol Arthrosc. 2016;24(11):3381-3386.

Sun C, Zhao Z, Lee WG, et al. Sensor-guided gap balance versus manual gap balance in primary total knee arthroplasty: a meta-analysis. J Orthop Surg Res. 2022 Apr 19;17(1):243.

Swank ML, Lehnert IE. Orthopedic personnel roles in the OR for computer assisted total knee arthroplasty. 2005 Oct;82(4):631-4,637-43.

Wood TJ, Winemaker MJ, Williams DS, et al. Randomized controlled trial of sensor-guided knee balancing compared to standard balancing technique in total knee arthroplasty. J Arthroplasty. 2021 Mar;36(3):953-957.

Policy History/Revision Information

Date	Summary of Changes
01/01/2025	**Coverage Rationale** • Replaced language indicating “the use of intra-operative *kinetic balance* sensor for implant stability during knee replacement arthroplasty is unproven and not medically necessary” with “the use of *an* intra-operative sensor for implant stability during knee replacement arthroplasty *and for improved knee function post-operatively* is unproven and not medically necessary” **Applicable Codes** • Revised description for CPT code 27599 • Replaced notation indicating “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” with “intra-operative use of *a* sensor for implant stability during knee replacement arthroplasty is considered incidental to the primary procedure being performed and is not eligible for separate reimbursement” **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version CS167OH.C

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.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines 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.