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Computer-Assisted Navigation for Orthopedic Procedures

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Computer-assisted surgical navigation for orthopedic procedures (e.g., use during a MAKOplasty procedure) **is considered experimental, investigational and/or unproven.**

EXCEPTION: This policy does not address the use of computer-assisted surgical navigation for orthopedic procedures of the spine.

Policy Guidelines

None.

Description

Computer-assisted navigation in orthopedic procedures describes the use of computer-enabled tracking systems to facilitate alignment in a variety of surgical procedures, including fixation of fractures, ligament reconstruction, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

Background

Implant Alignment for Knee Arthroplasty

For total knee arthroplasty, malalignment is commonly defined as a variation of more than 3° from the targeted position. Proper implant alignment is believed to be an important factor for minimizing long-term wear, the risk of osteolysis, and loosening of the prosthesis.

Computer-Assisted Navigation

The goal of computer-assisted navigation is to increase surgical accuracy and reduce the chance of malposition.

In addition to reducing the risk of substantial malalignment, computer-assisted navigation may improve soft tissue balance and patellar tracking. Computer-assisted navigation is also being investigated for surgical procedures with limited visibility such as placement of the acetabular cup in total hip arthroplasty, resection of pelvic tumors, and minimally invasive orthopedic procedures. Other potential uses of computer-assisted navigation for surgical procedures of the appendicular skeleton include screw placement for fixation of femoral neck fractures, high tibial osteotomy, and tunnel alignment during the reconstruction of the anterior cruciate ligament.

Computer-assisted navigation devices may be image-based or non-image-based. Image-based devices use preoperative computed tomography scans and operative fluoroscopy to direct implant positioning. Newer non-image-based devices use information obtained in the operating room, typically with infrared probes. For total knee arthroplasty, specific anatomic reference points are made by fixing signaling transducers with pins into the femur and tibia. Signal-emitting cameras (e.g., infrared) detect the reflected signals and transmit the data to a dedicated computer. During the surgery, multiple surface points are taken from the distal femoral surfaces, tibial plateaus, and medial and lateral epicondyles. The femoral head center is typically calculated by kinematic methods that involve the movement of the thigh through a series of circular arcs, with the computer producing a 3-dimensional model that includes the mechanical, transepicondylar, and tibial rotational axes. Computer-assisted navigation systems direct the positioning of the cutting blocks and placement of the prosthetic implants based on the digitized surface points and model of the bones in space. The accuracy of each step of the operation (cutting block placement, saw cut accuracy, seating of the implants) can be verified, thereby allowing adjustments to be made during surgery. For spine surgery, computer-assisted navigation may improve the accuracy of pedicle screw placement compared to conventional screw placement methods and limit radiation exposure to patients and surgical teams.

Computer-assisted navigation involves 3 steps: data acquisition, registration, and tracking.

Data Acquisition

Data can be acquired in 3 ways: fluoroscopically, guided by computed tomography scan or magnetic resonance imaging, or guided by imageless systems. These data are then used for registration and tracking.

Registration
Registration refers to the ability to relate images (i.e., radiographs, computed tomography scans, magnetic resonance imaging, or patients' 3-dimensional anatomy) to the anatomic 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 also 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 then provide real-time information of the position and orientation of tool alignment concerning the bony anatomy of interest.

VERASENSE™ (OrthoSensor) is a single-use device that replaces the standard plastic tibial trial spacer used in total knee arthroplasty. The device contains microprocessor sensors that quantify load and contact position of the femur on the tibia after resections have been made. The wireless sensors send the data to a graphic user interface that depicts the load. The device is intended to provide quantitative data on the alignment of the implant and soft tissue balancing in place of intraoperative "feel".

iASSIST® (Zimmer Biomet) is an accelerometer-based alignment system with a user interface built into disposable electronic pods that attach to the femoral and tibial alignment and resection guides. For the tibia, the alignment guide is fixed between the tibial spines and a claw on the malleoli. The relation between the electronic pod of the digitizer and the bone reference is registered by moving the limb into abduction, adduction, and neutral position. Once the information has been registered, the digitizer is removed, and the registration data are transferred to the electronic pod on the cutting guide. The cutting guide can be adjusted for varus/valgus alignment and tibial slope. A similar process is used for the femur. The pods use the wireless exchange of data and display the alignment information to the surgeon within the surgical field. A computer controller must also be present in the operating room.

Regulatory Status
Because computer-assisted navigation is a surgical information system in which the surgeon is only acting on the information that is provided by the navigation system, surgical navigation systems generally are subject only to 510(k) clearances from the U.S. Food and Drug Administration (FDA). As such, the FDA does not require data documenting the intermediate or final health outcomes associated with computer-assisted navigation. In contrast, robotic procedures, in which the actual surgery is robotically performed, are subject to the more rigorous requirement of the premarket approval application process.

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

Several navigation systems (e.g., PiGalileo™ Computer-Assisted Orthopedic Surgery System, PLUS Orthopedics; OrthoPilot® Navigation System, Braun; Navitrack® Navigation System, ORTHOsoft) have received the FDA clearance specifically for total knee arthroplasty. The FDA cleared indications for the PiGalileo system are representative. This system "is intended to be used in computer-assisted orthopedic surgery to aid the surgeon with bone cuts and implant positioning during joint replacement. It provides information to the surgeon that is used to place surgical instruments during surgery using anatomical landmarks and other data specifically obtained intraoperatively (e.g., ligament tension, limb alignment). Examples of some surgical procedures include but are not limited to:

- Total knee replacement supporting both bone referencing and ligament balancing techniques
- Minimally invasive total knee replacement."

FDA product code: HAW.

In 2013, the VERASENSE Knee System (OrthoSensor) and the iASSIST Knee (Zimmer Biomet) were cleared for marketing by the FDA through the 510(k) process. FDA product codes: ONN, OLO.

Several computer-assisted navigation devices cleared by the FDA are listed in the table below.

Table 1. Computer-Assisted Navigation Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(K) No.	Indication
Vital™ Navigation System	Zimmer Biomet Spine, Inc.	12/02/2019	K191722	Computer-assisted Navigation for Orthopedic Surgery
Stryker Navigation System With Spinemap Go Software Application, Fluoroscopy Trackers And Fluoroscopy Adapters. Spinemask Tracker	Stryker Corporation	02/14/2019	K183196	Computer-assisted Navigation for Orthopedic Surgery
NuVasive Pulse™ System	NuVasive Inc.	6/29/2018	K180038	Computer-assisted Navigation for Orthopedic Surgery
VERASENSE for Zimmer Biomet Persona	OrthoSensor Inc.	6/7/2018	K180459	Computer-assisted Navigation for Orthopedic Surgery

StealthStation™ S8 With Spine Software	Medtronic	5/01/2017	K170011	Computer-assisted Navigation for Orthopedic Surgery
NuVasive Next Generation NVM5® System	NUVASIVE Inc.	3/16/2017	K162313	Computer-assisted Navigation for Orthopedic Surgery
Stryker OrthoMap Versatile Hip System	Stryker Corporation	2/23/2017	K162937	Computer-assisted Navigation for Orthopedic Surgery
JointPoint™	JointPoint Inc.	8/3/2016	K160284	Computer-assisted Navigation for Orthopedic Surgery
ExactechGPS®	Blue Ortho	7/13/2016	K152764	Computer-assisted Navigation for Orthopedic Surgery
Verasense Knee System	OrthoSensor Inc.	4/15/2016	K150372	Computer-assisted Navigation for Orthopedic Surgery
iASSIST Knee System	Zimmer CAS	9/11/2014	K141601	Computer-assisted Navigation for Orthopedic Surgery
CTC TCAT®-TPLAN® Surgical System	Curexo Technology Corporation	8/18/2014	K140585	Computer-assisted Navigation for Orthopedic Surgery
Digimatch™ Orthodoc Robodoc® Encore Surgical System	Curexo Technology Corporation	5/27/2014	K140038	Computer-assisted Navigation for Orthopedic Surgery

Rationale

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

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The

quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

For many orthopedic surgical procedures, optimal alignment is considered an important aspect of long-term success. For example, misplaced tunnels in the anterior cruciate ligament or posterior cruciate ligament reconstruction or malalignment of arthroplasty components are some of the leading causes of instability and reoperation. In total hip arthroplasty (THA), the orientation of the acetabular component of the THA is considered critical, while for total knee arthroplasty (TKA), alignment of the femoral and tibial components and ligament balancing are considered important outcomes. Ideally, one would prefer controlled trials comparing the long-term outcomes, including stability and reoperation rates.

Computer-Assisted Navigation for Trauma or Fracture

Clinical Context and Therapy Purpose

The purpose of computer-assisted navigation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual alignment methods, in individuals who are undergoing orthopedic surgery for trauma or fracture.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are undergoing orthopedic surgery for trauma or fracture.

Interventions

The therapy being considered is computer-assisted navigation. Computer-assisted navigation in orthopedic procedures describes the use of computer-enabled tracking systems to facilitate alignment in a variety of surgical procedures, including fixation of fractures, ligament reconstruction, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

Comparators

Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/manual alignment methods include medical reduction procedures and conventional fluoroscopic guidance (i.e., C-arm fluoroscopy).

Outcomes

The general outcomes of interest are symptoms, morbid events, and functional outcomes.

The existing literature evaluating computer-assisted navigation as a treatment for patients who are undergoing orthopedic surgery for trauma or fracture has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Computer-assisted surgery has been described as an adjunct to pelvic, acetabular, or femoral fractures. For example, fixation of these fractures typically requires percutaneous placement of screws or guidewires. Conventional fluoroscopic guidance (i.e., C-arm fluoroscopy) provides imaging in only 1 plane. Therefore, the surgeon must position the implant in 1 plane and then get additional images in other planes in a trial-and-error fashion to ensure that the device has been properly placed. This process adds significant time in the operating room and radiation exposure. Computer-assisted surgery may permit minimally invasive fixation and provide more versatile screw trajectories with less radiation exposure. Therefore, computed-assisted surgery is considered an alternative to the existing image guidance using C-arm fluoroscopy.

Observational Study

Ideally, investigators would conduct controlled trials comparing operating room time, radiation exposure, and long-term outcomes of those whose surgery was conventionally guided using C-arm versus image-guided using computer-assisted surgery. While several in vitro and review studies had been published, (1-3) only 2 studies of computer-assisted surgery in trauma or fracture cases were identified. (4, 5) Computer-assisted navigation for internal fixation of femoral neck fractures was retrospectively analyzed in 2 cohorts of consecutive patients (20 each, performed from 2001 to 2003, at 2 different campuses of a medical center) who underwent internal fixation with 3 screws for a femoral neck fracture. (4) Three of 5 measurements of parallelism and neck coverage were significantly improved by computer-assisted navigation; they included a larger relative neck area held by the screws (32% vs. 23%) and less deviation on the lateral projection for both the shaft (1.7° vs. 5.2°) and the fracture (1.7° vs. 5.5°) screw angles, all respectively. Slight improvements in anteroposterior screw angles (1.3° vs. 2.1° and 1.3° vs. 2.4°, respectively) were not statistically significant. There were 2 reoperations in the computer-assisted navigation group and 6 in the conventional group. Complications (collapse, subtrochanteric fracture, head penetration, osteonecrosis) were lower in the computer-assisted navigation group (3 vs. 11, respectively).

A retrospective comparative study by Swartman et al. (2021) investigated differences in conventional fluoroscopy-assisted percutaneous management (n=13) of acetabular fractures to 3-dimensional (3D)-computer navigated management (n=24). (5) Both groups demonstrated a significant reduction in fracture gaps and steps post-intervention. However, there were no significant differences between groups in outcomes related to fracture reduction or screw positions.

Section Summary: Computer-Assisted Navigation for Trauma or Fracture

There is limited literature on the use of computer-assisted navigation for trauma or fractures. Additional controlled studies that measure health outcomes are needed to evaluate this technology.

Computer-Assisted Navigation for Anterior Cruciate Ligament or Posterior Cruciate Ligament Reconstruction

Clinical Context and Therapy Purpose

The purpose of computer-assisted navigation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual alignment methods, in individuals who are undergoing ligament reconstruction.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are undergoing ligament reconstruction.

Interventions

The therapy being considered is computer-assisted navigation. Computer-assisted navigation in orthopedic procedures describes the use of computer-enabled tracking systems to facilitate alignment in a variety of surgical procedures, including fixation of fractures, ligament reconstruction, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

Comparators

Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/manual alignment methods include medical reduction procedures.

Outcomes

The general outcomes of interest are symptoms, morbid events, and functional outcomes.

The existing literature evaluating computer-assisted navigation as a treatment for patients who are undergoing ligament reconstruction has varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 2 years of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Eggerding et al. (2014) published a Cochrane review that compared the effects of computer-assisted navigation with conventional operating techniques for anterior cruciate ligament or posterior cruciate ligament reconstruction. (6) Five RCTs (N=366 participants) on anterior cruciate ligament reconstruction were included in the updated review; no studies involved posterior cruciate ligament reconstruction. The quality of evidence ranged from moderate to very low. Pooled data showed no statistically or clinically relevant differences in self-reported health outcomes (International Knee Documentation Committee [IKDC] subjective scores and Lysholm Knee Scale scores) at 2 or more years of follow-up. No significant differences were found for secondary outcomes, including knee stability, range of motion, and tunnel placement. Overall, there was insufficient evidence to advise for or against the use of computer-assisted navigation. Four of the 5 trials included in the Cochrane review are described in Tables 2 and 3.

Yavari et al. (2023) published a systematic review of 11 studies (N=775) evaluating technology-assisted anterior cruciate ligament reconstruction including computer-assisted navigation, virtual reality, augmented reality, 3D printing, and robotics. (7) Five studies (N=454) evaluated image-free computer-assisted navigation. Subjective IKDC scores were improved in the technology-assisted surgery group (mean difference, 1.97; 95% confidence interval [CI], 0.27 to 3.66; p=.02); however, the authors noted that a minimally clinically important difference of 9 has been previously published. Objective IKDC scores were not significantly different between groups (risk ratio, 1.02; 95% CI, 0.98 to 1.06). Notably, results specific to computer-assisted navigation were not analyzed.

Randomized Controlled Trials

Plaweski et al. (2006) reported on a trial that randomized 60 patients to manual or computer-assisted guidance for tunnel placement with follow-up at 1, 3, 6, 12, 18, and 24 months. (8) There were no differences between groups in measurements of laxity. However, there was less variability in side-to-side anterior laxity in the navigated group (e.g., 97% were within 2 mm of laxity in the navigated group vs. 83% in the conventional group at an applied force of 150 N). There was a significant difference in the sagittal position of the tibial tunnel (distance from the Blumensaat line, 0.4 mm vs. -1.2 mm, respectively), suggesting possible impingement in extension for the conventional group. At the final follow-up (24 months), all knees had normal function, with no differences observed between groups.

Hart et al. (2008) compared biomechanical radiographic with functional results in 80 patients randomized to anterior cruciate ligament reconstruction using computer-assisted navigation (n=40) or to the standard manual targeting technique (n=40). (9) The blinded evaluation found more exact bone tunnel placement with computer-assisted navigation, but no overall difference in biomechanical stability or function between groups.

Other studies have found no significant improvement in the accuracy of tunnel placement when using computer-assisted navigation. Meuffels et al. (2012) reported on a double-blind controlled trial that randomized 100 patients to conventional or computer-assisted surgery. (10) Evaluation by 3-dimensional computed tomography (CT) found no significant difference between groups for the accuracy or the precision of the femoral and tibial tunnel placement.

Table 2. Summary of Characteristics of Key Randomized Controlled Trials Comparing Computer-Assisted Navigation With Manual Placement for Anterior or Posterior Cruciate Ligament Reconstruction

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Plaweski et al. (2006) (8)	USA	1	Oct 2014 to Jan 2016	Patients (N=60) undergoing ACL reconstruction.	CAN (n=30)	Manual placement (n=30)
Hart et al. (2008) (9)	Czech Republic	1	NR	Patients (N=80) undergoing ACL reconstruction for chronic rupture of the ACL; only chronic ACL-insufficiency knees were included in the study (>6 mo after injury). Other inclusion criteria were no other prior or simultaneous intra-articular surgical procedure, no cartilage degeneration of meniscal tear, and a normal contralateral knee. Ages ranged from 16 to 39 years with a mean of 29.4. Mean body weight was 74 kg.	CAN (n=40)	Manual placement (n=40)
Meuffels et al.	Netherlands	1	Jan 2007-	Patients (N=100) ≥18 years of age and	CAN (n=49)	Conventional (n=51)

(2012) (10)			Nov 2009	eligible for primary ACL reconstruction without additional PCL or lateral collateral ligament injury were included.		
Mauch et al. (2007) (11)	Germany	1	Dec 2003-April 2004	Athletes aged 18 to 49 years (N=53) with ACL rupture and no complex injuries of knee with additional injury of PCL, injury of posterior lateral complex, or third-degree injury of intra-articular ligament.	CAN (n=24)	Manual placement (n=29)

ACL: anterior cruciate ligament; CAN: computer-assisted navigation; NR: not reported; PCL: posterior cruciate ligament.

Table 3. Summary of Key Randomized Controlled Trials Comparing Computer-Assisted Navigation With Manual Placement for Anterior or Posterior Cruciate Ligament Reconstruction

Study	IKDC	Laxity <2 mm	Lachman Test (0)	Lachman Test (2+)	Placement of the Femoral Tunnel	Tibial Tunnel Border
Plaweski et al. (2006) (8)						
CAN (n=26 knees)					NR	Mean, ATB, -0.2 (5 to +4)
Mean Level A laxity level (n=26 knees)	mean, 1.3 mm at 200 N; p=.49	96.7%; p=.295	23 (76.7)	1 (3.3)		
Manual (n=22 knees)					NR	mean ATB, 0.4 (0 to 3)
Mean Level A laxity level	mean, 1.5 mm at 200 N; p=.49	83%; p=.292	26 (87)	0 (0)		

(n=22 knees)						
Hart et al. (2008) (9)						
CAN (n=40)	Mean post-op Improvement: 76.5 points; SD, 10.3; p<.01	Mean difference in anterior laxity compared with contralateral (healthy) knee: 1.43 mm (range, 0 to 4 mm)	12 (30%)	14 (35%)	Ideal *a/t* value: 24.8% Mean, 25.5% (SD, 1.63)	Zone 2 location: 39 (97.5%)
Manual (n=40)	Mean post-op Improvement: 73.1 points; SD, 11.8; p<.01	Mean difference in anterior laxity compared with contralateral (healthy) knee: 1.24 mm (range, -2 to 5 mm)	18 (45%)	10 (25%)	Ideal *a/t* value: 24.8% Mean, 27% (SD, 2.76)	Zone 2 location: 38 (95.0%)
Meuffels et al. (2012) (10)						
CAN (n=49)	NR	NR	NR	NR	Mean 39% of the proximal distance on the intra-condylar axis	Distance from most medial edge: 42.7% ± 3.6%
Manual (n=51)	NR	NR	NR	NR	Mean 39.7% of the proximal distance on the intracondylar axis	Distance from most medial edge: 42.6% ± 5.7%
Mauch et al. (2007) (11)						
CAN (n=24)	NR	NR	NR	NR	NR	21.2 mm (32.2%)

Manual (n=29)	NR	NR	NR	NR	NR	19.4 mm (29.7%)
p value	NR	NR	NR	NR	NR	.18

a/t value: ratio identifies anterior-posterior femoral tunnel placement; ATB: anterior tension band plate; CAN: computer-assisted navigation; IKDC: International Knee Documentation Committee; NR: not reported; Post-op: postoperative; SD: standard deviation.

The purpose of the limitations tables (see Tables 4 and 5) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 4. Summary of Study Relevance Limitations in Key Randomized Controlled Trials Comparing Computer-Assisted Navigation With Manual Placement

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Plaweski et al. (2006) (8)	3. Limited demographic information provided.				
Hart et al. (2008) (9)	3. The study setting and source of study participants are missing (as is the referral pattern)–this could create referral-filter bias.				
Meuffels et al. (2012) (10)	3. Study population is incompletely characterized.	2. Inconsistent fidelity of intervention protocol: There is a lack of consistency as to the best method for performing the intervention.			
Mauch et al. (2007) (11)	1, 4. Intended use population is			5, 6. Clinically significant	1, 2. Follow-up was 4 days, not

	unclear. Limited to athletes.			difference not prespecified or mentioned.	long enough to determine intermediate- or long-term outcomes.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population is not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 5. Summary of Design and Conduct Limitations in Key Randomized Controlled Trials Comparing Computer-Assisted Navigation With Manual Placement

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Plaweski et al. (2006) (8)		1. Unclear whether patients were blinded.				3. Confidence intervals not reported. 4. Comparison of treatment effect not provided.
Hart et al. (2008) (9)	3. Randomization techniques are not described in any manner within the text.				1. Power calculations not reported.	3. Confidence intervals not reported.
Meuffels et al. (2012) (10)						
Mauch et al.	4. Drawing lots is a weak	1,2,3. Blinding is not			1. Power calculations	3. Confidence intervals

(2007) (11)	method of allocation.	mentioned at all.			not reported.	not reported.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Computer-Assisted Navigation for Anterior Cruciate Ligament or Posterior Cruciate Ligament Reconstruction

The evidence on computer-assisted navigation for anterior cruciate ligament or posterior cruciate ligament reconstruction includes a systematic review of 5 RCTs. These RCTs, of moderate- to low-quality, did not consistently demonstrate more accurate tunnel placement with computer-assisted navigation. No studies have shown an improvement in functional outcomes or need for revision when computer-assisted navigation is used for anterior cruciate ligament or posterior cruciate ligament reconstruction.

Computer-Assisted Navigation for Total Hip Arthroplasty and Periacetabular Osteotomy

Clinical Context and Therapy Purpose

The purpose of computer-assisted navigation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual alignment methods, in individuals who are undergoing THA and periacetabular osteotomy.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are undergoing THA and periacetabular osteotomy.

Interventions

The therapy being considered is computer-assisted navigation. Computer-assisted navigation in orthopedic procedures describes the use of computer-enabled tracking systems to facilitate alignment in a variety of surgical procedures, including fixation of fractures, ligament

reconstruction, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

Comparators
Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/manual alignment methods include medical reduction procedures.

Outcomes
The general outcomes of interest are symptoms, morbid events, and functional outcomes.

The existing literature evaluating computer-assisted navigation as a treatment for patients who are undergoing THA and periacetabular osteotomy has varying lengths of follow-up, ranging from 6 to 40 months. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Kunze et al. (2022) published a systematic review comparing surgical time, short-term adverse events, and implant placement accuracy between manual, robotic-assisted, and computer-navigated THA. (12) Seven RCTs were identified comparing computer-assisted navigation and manual THAs. Table 6 outlines the studies included comparing computer-assisted THA and manual THA. Characteristics and results specific to computer-assisted navigation are shown in Tables 7 and 8, respectively. In brief, manual THA resulted in significantly shorter surgical times and a similar incidence of complications and revisions compared to computer-assisted THA. However, computer-assisted navigation THA led to increased precision in the placement of acetabular implants. These results are limited by a lack of recent RCTs, inability to conduct meta-analysis of patient-reported outcome measures, and use of the Lewinnek safe zone as a benchmark for proper acetabular implant positioning, which may not be appropriate in all patients. Additionally, there were a variety of computer-assisted navigation systems used across RCTs, limiting conclusions regarding any particular system.

Table 6. Comparison of RCTs Included in Systematic Reviews and Meta-Analyses for Computer-Assisted Navigation for THA

Study	Kunze et al. (2022)[a] (12)
Leenders et al. (2002)	●

Gurgel et al. (2014)	●
Lass et al. (2014)	●
Renkawitz et al. (2015)	●
Parratte et al. (2016)	●
Weber et al. (2016)	●
Verdier et al. (2016)	●

RCT: randomized controlled trial; THA: total hip arthroplasty.

[a] Only articles comparing computer navigation and manual total hip arthroplasty procedures are included in table.

Table 7. Systematic Reviews and Meta-Analyses for Computer-Assisted Navigation for THA: Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration, mean
Kunze et al. (2022) (12)	2008-2019	7	Computer-assisted navigation THA compared to manual THA with at least 1-year follow-up.	598 (40 to 135)	RCT	4.3 years (range, 1 to 14.2 years)[a]

RCT: randomized controlled trial; THA: total hip arthroplasty

[a] Mean duration includes all studies included in systematic review, including robotic-assisted THA studies.

Table 8. Systematic Reviews and Meta-Analyses for Computer-Assisted Navigation for THA: Results

Study	Operation length, mins	All-cause complications	All-cause revisions	Acetabular implant positioning (% of acetabular cups placed in safe zone)
Kunze et al. (2022) (12)				
Total N	373 (3 studies)	NR (11 studies)	598 (7 studies)	178 (3 studies)
Manual THA	mean, 86.6 mins	Total=38 (6.6%)	Total=2	46/89 (52%)
Computer-assisted THA	mean, 95.7 mins	Total=5 (1.7%)	Total=3	70/89 (79%)
Pooled effect (95% CI)	SMD, 8.55 (3.49 to 13.60)	OR, 0.83 (0.23 to 2.99)	OR, 1.15 (0.30 to 4.42)	ES, 0.79 (0.69 to 0.86)
p-value	<.001	.781	.840	.02
I^2 (p)				*0%* (.29)

CI: confidence interval; ES: effect size; NR: not reported; OR: odds ratio; SMD: standard mean difference; THA: total hip arthroplasty.

Nonrandomized Studies

Manzotti et al. (2011) compared leg length restoration in a matched-pair study. (13) Forty-eight patients undergoing THA with computer-assisted navigation were compared with patients who were matched for age, sex, arthritis level, preoperative diagnosis, and preoperative leg length discrepancy and underwent conventional freehand THA using the same implant in the same period. The mean preoperative leg length discrepancy was 12.17 mm in the computer-assisted navigation group and 11.94 mm in the standard group. Surgical time was increased by 16 minutes in the computer-assisted navigation group (89 minutes vs. 73 minutes). There was a significant decrease in both the mean postoperative leg length discrepancy (5.06 mm vs. 7.65 mm) and the number of cases with a leg length discrepancy of 10 mm or more (5 patients vs. 13 patients), all respectively. Outcomes at 40-month follow-up (range, 7 to 77 months) did not differ significantly for the Harris Hip Score (88.87 vs. 89.73) or the 100-point normalized Western Ontario and McMaster Universities Arthritis Index score (9.33 vs. 13.21; p=.050), all respectively. Longer follow-up with a larger number of subjects is needed to determine whether computer-assisted navigation influences clinical outcomes.

Minimally Invasive Total Hip Arthroplasty

Systematic Reviews

It has been proposed that computer-assisted navigation might overcome the difficulties of reduced visibility of the surgical area associated with minimally invasive procedures. Ulrich et al (2007) summarized study results that compared outcomes from minimally invasive THA using computer-assisted navigation with standard THA. (14) Seventeen studies were described in this evidence-based review, including 9 prospective comparisons, 7 retrospective comparisons, and 1 large (N=100) case series. Reviewers concluded that alignment with minimally invasive computer-assisted navigation appears to be at least as good as standard THA, although the more consistent alignment must be balanced against the expense of the computer systems and increased surgical time.

Randomized Controlled Trials

Reininga et al. (2013) reported short-term outcomes of minimally invasive THA approach with computer-assisted navigation (n=35) compared with conventional posterolateral THA (n=40). (15) This randomized comparison found no group differences in the recovery of gait at up to 6 months postsurgery.

Periacetabular Osteotomy

Randomized Controlled Trials

Hsieh et al. (2006) reported on 36 patients with symptomatic adult dysplastic hip who were randomized to CT-based navigation or the conventional technique for periacetabular osteotomy. (16) An average of 0.6 intraoperative radiographs were taken in the navigated group compared with 4.4 in the conventional group, resulting in a total surgical time that was 21 minutes shorter for computer-assisted navigation. There were no differences between

groups for correction in femoral head coverage or functional outcomes (pain, walking, range of motion) at 24 months.

Total Hip Resurfacing

Randomized Controlled Trials

Stiehler et al. (2013) reported on short-term radiographic and functional outcomes from a randomized comparative trial of total hip resurfacing using computer-assisted navigation and conventional total hip resurfacing in 75 patients. (17) For most of the radiographic measures, there were no significant differences between the computer-assisted navigation and conventional total hip resurfacing groups. There were fewer outliers (≥5°) for the femoral component with computer-assisted navigation (11%) compared with conventional placement (32%). At 6-month follow-up, there were no differences between groups in the final Western Ontario and McMaster Universities score or Harris Hip Score. The computer-assisted navigation group did show a greater percentage improvement in the Western Ontario and McMaster Universities scores and Harris Hip Score due to differences between groups at baseline.

Section Summary: Computer-Assisted Navigation for Total Hip Arthroplasty and Periacetabular Osteotomy

Relatively few RCTs have evaluated computer-assisted navigation for hip procedures. Although there was an early interest in this technology, no recent RCTs have been identified. There is inconsistent evidence from systematic reviews of these small trials on whether computer-assisted navigation improves alignment with conventional or minimally invasive THA. One RCT found improved alignment when computer-assisted navigation was used for hip resurfacing, but there was little evidence of improved outcomes at short-term follow-up. Overall, improved health outcomes have not been demonstrated with computer-assisted navigation for any hip procedures.

Computer-Assisted Navigation for Total Knee Arthroplasty

Clinical Context and Therapy Purpose

The purpose of computer-assisted navigation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual alignment methods, in individuals who are undergoing TKA.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are undergoing TKA.

Interventions

The therapy being considered is computer-assisted navigation. Computer-assisted navigation in orthopedic procedures describes the use of computer-enabled tracking systems to facilitate alignment in a variety of surgical procedures, including fixation of fractures, ligament reconstruction, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

Comparators
Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/manual alignment methods include medical reduction procedures.

Outcomes
The general outcomes of interest are symptoms, morbid events, and functional outcomes.

The existing literature evaluating computer-assisted navigation as a treatment for patients who are undergoing TKA has varying lengths of follow-up, ranging from 1 to 8 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

Alignment of a knee prosthesis can be measured along several different axes, including the mechanical axis, and the frontal and sagittal axes of both the femur and tibia.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
A systematic review conducted by Xie et al. (2012) included 21 randomized trials (N=2658 patients) that reported on clinical outcomes with or without the use of computer-assisted navigation (Table 9). (18) Most trials included in the review had short-term follow-up. Surgical time was significantly increased with computer-assisted navigation for TKA, but there was no significant difference between approaches in total operative blood loss, the Knee Society Score, or range of motion (Table 10).

Rebal et al. (2014) conducted a meta-analysis of 20 RCTs (N=1713 knees) that compared imageless navigation technology with conventional manual guides (Table 9). (19) The majority of included studies had a low risk of bias. The improvement in Knee Society Score was statistically superior in the computer-assisted navigation group at 3 months and 12 to 32 months (Table 10). However, these improvements did not achieve the minimal clinically significant difference, defined as a change of 34.5 points.

Namireddy et al. (2024) conducted a systematic review and meta-analysis comparing computerized versus traditional TKA using the Knee Society Score and the Western Ontario and McMaster Universities Osteoarthritis Index. (20) A pooled analysis showed no significant

difference in the mean monthly change in Knee Society Score between groups (difference, 0.20; 95% CI, -0.53 to 0.93; p=.59) with high heterogeneity (I^2=85%). Similarly, no significant difference was observed in the mean monthly change in Western Ontario and McMaster Universities Osteoarthritis Index (difference, 0.17; 95% CI, -0.46 to 0.79; p=.60) with moderate heterogeneity (I^2=28%).

Table 9. Characteristics of Systematic Reviews and Meta-Analyses Investigating Total Knee Arthroplasty

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Xie et al. (2012) (18)	PubMed and EMBASE through August 2011	21	Included 2658 patients. Among these, 1376 were randomly allocated to the computer-assisted TKA group and 1282 to the conventional group	2658 (25 to 120)	RCT	NR
Rebal et al. (2014) (19)	PubMed, EMBASE, Scopus, and CENTRAL through December 2012	20	Included a combined 869 knees in the computer-assisted groups, and 844 knees in the control groups for a total of 1713 knees analyzed	1713 knees (46 to 166)	RCT	3 mos and 12 to 32 mos
Namireddy et al. (2024) (20)	PubMed and Cochrane library through November 2023	5	Included 339 participants; 173 received computer-assisted TKA and 166 received traditional TKA	339 (52 to 95)	RCT	3 to 12 mos

NR: not reported; mos: months; RCT: randomized controlled trial; TKA: total knee arthroplasty.

Table 10. Results of Systematic Reviews and Meta-Analyses Investigating Total Knee Arthroscopy

Study	Knee Society Score	Operative Time
Xie et al. (2012) (18)		
Mean standard difference	4.47	14.68

95% CI	-1.05 to 9.99				11.74 to 17.62	
P-value	.36				<.0001	
	CAN		**Conventional**		**CAN (min)**	**Conventional (min)**
	3 Months	**12 to 32 Months**	**3 Months**	**12 to 32 Months**		
Rebal et al. (2014) (19)						
Mean	68.5	53.1	58.1	45.8	101.6	83.3
95% CI			1.13 to 19.78	2.87 to 11.90		11.84 to 24.60
P-value			.03	<.01		<.01
Namireddy et al. (2024) (20)						
	Knee Society Score, monthly rate of change	**WOMAC score, monthly rate of change**				
Mean standard difference	0.20	0.17				
95% CI	-0.53 to 0.93	-0.46 to 0.79				
p-value	.59	.60				

CAN: computer-assisted navigation; CI: confidence interval; min: minutes; WOMAC: Western Ontario McMaster Universities Osteoarthritis Index.

Effect of Computer-Assisted Navigation on Mid- to Long-Term Outcomes

Randomized Controlled Trials

RCTs comparing outcomes at 4 to 12 years follow-up generally have shown a reduction in the number of outliers with computer-assisted navigation, but little to no functional difference between the computer-assisted navigation and conventional TKA groups.

Three trials comparing computer-assisted navigation and conventional surgery reported on outcomes at 4 to 5 years follow-up (N=67 to 107). Blakeney et al. (2014), reporting 46-month follow-up for 107 patients (21), found a trend toward higher scores on the Oxford Knee Questionnaire with computer-assisted navigation, with a mean score of 40.6 for the computer-assisted navigation group compared with 37.6 and 36.8 in extramedullary and intramedullary control groups, respectively. There were no significant differences in the 12-Item Short-Form Health Survey Physical Component or Mental Component Summary scores. The trial was underpowered, and the clinical significance of this trend for the Oxford Knee Questionnaire is unclear. Lutzner et al. (2013), reporting on 5-year follow-up for 67 of 80 patients (22), found a significant decrease in the number of outliers with computer-assisted navigation (3 vs. 9; p=.048) but no significant differences between groups on the Knee Society Score or Euroquol

quality of life questionnaire. At 10-years post-surgery, a follow-up study (Beyer et al. 2021) of 50 patients originally included in the Lutzner et al. 2013 study showed no significant differences in the number of outliers between groups, patient-reported outcomes from the Knee Society Score of Euroquol quality of life questionnaire, and no differences in revision risk. (23) Cip et al. (2014) found a significant decrease in malalignment with computer-assisted navigation, but no significant differences in implant survival or consistent differences in clinical outcome measures between the navigated (n=100) and conventional (n=100) total knee arthroplasty groups at minimum 5-year follow-up. (24)

Four additional trials comparing computer-assisted and conventional surgery reported outcomes after 8 to 12 years follow-up (N=60 to 200). Hsu et al. (2019) reported similar clinical and functional outcomes with the 2 procedures after a mean 8.1-year follow-up, although computer-assisted navigation achieved better radiographic alignment and fewer outliers. (25) They suggested that TKA with computer-assisted navigation may not provide an advantage to the typical osteoarthritis patient, but it may benefit certain patients, such as those with severe deformity of the knee joint, extra-articular deformities, and severe femoral bowing. The study was limited by its solely Asian patient population, single-center, and small sample size. Song et al. (2016) also reported on a reduction in the number of outliers with computer-assisted navigation (7.3% vs. 20%; p=.006), with no significant differences in clinical outcomes at 8-year follow-up. (26) The trial, which assessed 80 patients (88 knees) was powered to detect a 3-point difference in Knee Society Score results. Cip et al. (2018) published the results of a prospective randomized trial (N=200) comparing conventional TKA with computer-assisted TKA with a mean follow-up of 12 years postoperatively. (27) The trial was aimed at determining the long-term outcomes of computer-assisted navigation for TKA as a tool to expedite long-term survival based on improved postoperative implantation. The follow-up rate was 75%. No difference in long-term TKA survival was found between the conventional group (91.5%) and the computer-assisted navigation group (98.2%) at 12 years (p=.181). In a single-blinded, prospective RCT, Farhan-Alanie et al. (2023) compared conventional TKA (n=98) with computer-assisted TKA (n=101), with a mean follow-up of 10 years. (28) Over the 10-year period, there were 23 deaths (22.8%) in the computer-assisted group and 30 deaths (30.6%) in the conventional cohort. At the 10-year follow-up, the authors found no difference in revision rates (4.0% computer-navigation vs 6.1% conventional; p=.429) or clinical outcomes, including Oxford Knee Scores, American Knee Society Scores, or mental and physical scores on the 36-item Short-Form survey between groups.

Comparative Studies

Results from observational studies have generally been consistent with the systematic reviews and RCTs. (29-34) The longest of these observational studies, conducted by Dyrhovden et al. (2016), assessed survivorship and the relative risk of revision at 8-year follow-up for 23,684 cases from the Norwegian Arthroplasty Register for patients treated with computer-assisted navigation or conventional surgery. (33) Overall prosthesis survival and risk of revision were similar for both groups, although revisions due to malalignment were reduced with computer-assisted navigation (relative risk, 0.5; 95% CI, 0.3 to 0.9; p=.02). There were no significant differences between groups for other reasons for revision (e.g., aseptic loosening, instability,

periprosthetic fracture, decreased range of motion). At 8 years, the survival rate was 94.8% (95% CI, 93.8% to 95.8%) in the computer-assisted navigation group and 94.9% (95% CI, 94.5% to 95.3%) for conventional surgery.

In the largest observational study, Antonios et al. (2020) compared Medicare data from 75,709 patients who underwent a computer navigated TKA with a matched cohort of 75,676 Medicare patients who underwent conventional TKA. (34) There was no statistically significant difference in 5-year event-free survival in all-cause revisions between groups (95.1% vs. 94.7%; p=.06) However, there was a small difference in revisions due to mechanical complications (96.1% vs. 95.7%; p=.02) but not in revisions due to periprosthetic joint infection (97.9% vs. 97.9%; p=.30).

A retrospective comparison cohort study by Webb et al. (2021) compared conventional TKA cases (n=219,880) to computer navigated TKA cases (n=5243) that occurred from 2008 through 2016 and were documented in the American College of Surgeons National Surgical Quality Improvement Program database. (35) In univariate analysis of unmatched cohorts, rates of composite serious morbidities and death or serious morbidity were significantly higher in the conventional TKA group than the computer navigated group (8.47% vs. 7.54%; p=.016). In multivariable regression analysis, computer navigated TKA was found to be significantly associated with lower rates of serious morbidity (odds ratio [OR], 0.83; p=.001), death or serious morbidity (OR, 0.82; p<.001) and length of stay (OR, 0.86; p=.024). Propensity score matching identified 4811 case pairs of conventional versus computer navigated TKA. Propensity-matched analyses demonstrated no significant difference in mortality, length of operation time, length of stay, or rates of reoperation or readmission. The composite rate of complications was 18% less in the computer navigated group compared to the conventional TKA group (p=.009).

Section Summary: Computer-Assisted Navigation for Total Knee Arthroplasty
Based on systematic reviews, a large number of RCTs have assessed outcomes for TKA using computer-assisted navigation or conventional TKA without computer-assisted navigation. Results are consistent in showing reductions in the proportion of outliers greater than 3° in alignment. Results from individual RCTs and cohort studies up to 12 years postoperatively have not shown that these differences in alignment lead to improved patient outcomes.

Summary of Evidence
For individuals who are undergoing orthopedic surgery for trauma or fracture and receive computer-assisted navigation, the evidence includes 2 retrospective studies, reviews, and in vitro studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Functional outcomes were not included in the first clinical trial, although it did note fewer complications with computer-assisted navigation versus conventional methods. The second trial found no differences between groups in rates of fracture reduction or screw positions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing ligament reconstruction and receive computer-assisted navigation, the evidence includes a systematic review of 5 randomized controlled trials (RCTs) of computer-assisted navigation versus conventional surgery for anterior and posterior cruciate ligament. Relevant outcomes are symptoms, morbid events, and functional outcomes. Trial results showed no consistent improvement of tunnel placement with computer-assisted navigation, and no trials looked at functional outcomes or need for revision surgery with computer-assisted navigation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing hip arthroplasty and periacetabular osteotomy and receive computer-assisted navigation, the evidence includes systematic reviews of older RCTs and comparison studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Evidence on the relative benefits of computer-assisted navigation with conventional or minimally invasive total hip arthroplasty (THA) is inconsistent, and more recent RCTs are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing total knee arthroplasty (TKA) and receive computer-assisted navigation, the evidence includes RCTs, systematic reviews of RCTs, and comparative studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. The main difference found between TKA with computer-assisted navigation and TKA without computer-assisted navigation is increased surgical time with computer-assisted navigation. Few differences in clinical and functional outcomes were seen at up to 12 years post-procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Academy of Orthopedic Surgeons

The American Academy of Orthopedic Surgeons updated guidelines in 2022 on surgical management of osteoarthritis of the knee. (36) Related to computer-assisted surgical navigation, the guidelines state there is no difference in outcomes, function, or pain between computer-navigation and conventional techniques for total knee arthroplasty (strength of evidence: strong; strength of recommendation: moderate), and make no specific recommendation related to its use. The guidelines note that the advantages of surgical navigation remain unclear.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and/or unpublished trials that might influence this policy are listed in Table 11.

Table 11. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date

NCT06062615	Randomized Pilot Study Investigating Early Functional Outcomes With the Use of Robotic Assisted Versus Conventional Total Knee Arthroplasty	30	Dec 2023
NCT06036212	A Prospective, Single-blind, Multi-Centre, Randomised Controlled Study to Evaluate the Clinical and Patient Reported Outcomes Following Unicompartmental Knee Arthroplasty With a Robotic Assisted Technique	280	Mar 2036
NCT03628378	Randomized, Controlled, Single Center Observational Study to Compare the Safety and Performance of Navigation-assisted OrthoPilot® Elite and Robotic-assisted MAKO® Total Knee Arthroplasty	140	Jun 2025
NCT02717299[a]	Making Sense Out of Total Knee Sensor Assisted Technology: A Randomized Control Trial	78	Apr 2021 (recruitment status unknown)
NCT04960345	Comparison of Accuracy and Clinical Outcomes Between Brainlab Knee 3 Computer-assisted Navigation Systems and Conventional Instruments in TKA: a Prospective Cohort Study	188	Dec 2023
NCT01469299[a]	Prospective Study Measuring Clinical Outcomes of Knee Arthroplasty Using the VERASENSE™ Knee System	285	Dec 2016 (updated Jan 2017)
NCT03668756	Comparison of Computer-Assisted Navigation and Conventional Instrumentation for Bilateral Total Knee Arthroplasty: The Functional Outcome of Mid-Term Follow-up Study	56	Aug 2018
NCT02190435[a]	Computer-Assisted Navigation for Intramedullary Nail Fixation of Intertrochanteric Femur Fractures	65	Jan 2016
NCT03817632[a]	Prospective, Multicenter, Observational, Comparative Clinical Trial on the Equivalence of Two Different OrthoPilot® Navigation System Generations Applied for Computer-assisted Total Knee Arthroplasty	217	Oct 2022

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	20985, 0054T, 0055T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
12/01/2025	Document updated. Minor editorial changes made to Coverage without change to intent. Added reference 20.
02/01/2025	Document updated with literature review. Coverage statement changed from "Computer-assisted surgical navigation for orthopedic procedures, including but not limited to use during a MAKOplasty procedure, is considered experimental, investigational and/or unproven" to "Computer-assisted surgical navigation for orthopedic procedures specific to the pelvis and appendicular skeleton, including but not limited to use during a MAKOplasty procedure, is considered experimental, investigational and/or unproven." Added a NOTE to Policy Guidelines stating "This policy does not address the use of computer-assisted surgical navigation for orthopedic procedures of the spine." Added reference 7; removed multiple references.
05/15/2024	Document updated with literature review. Coverage statement changed from "Computer-assisted surgery for orthopedic procedures of the pelvis and appendicular skeleton is considered experimental, investigational and/or unproven." to "Computer-assisted surgical navigation for orthopedic procedures, including but not limited to use during a MAKOplasty procedure, is considered experimental, investigational and/or unproven." Added references 5, 11, 21, 26, and 33-44.
07/15/2022	Reviewed. No changes.
09/15/2021	Document updated with literature review. Coverage unchanged. Reference 31 added.
01/01/2021	Document updated with literature review. Coverage unchanged. References 22, 23 added.
08/01/2019	Reviewed. No changes.
07/15/2018	Document updated with literature review. Coverage unchanged. References 26, 32 added. Title changed from: Computer Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure.
04/15/2017	Reviewed. No changes.
10/01/2016	Document updated with literature review. Coverage unchanged.
08/15/2015	Reviewed. No changes.

03/01/2014	Document updated with literature review. Coverage unchanged.
01/15/2011	Document updated with literature review. Coverage unchanged.
01/15/2008	Revised/updated entire document
04/15/2005	New Medical document