7.01.96	Computer-Assisted Navigation for Orthopedic Procedures		
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Section:	7.0 Surgery	**Page:**	Page 1 of 27

Policy Statement

Computer-assisted surgical navigation for orthopedic procedures is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

The coding for this navigation includes one category I CPT code and two category III CPT codes:

- **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)

All of the codes are intended to be used in addition to the code for the primary procedure.

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.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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) 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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
iASSIST Knee System	Zimmer CAS	9/11/2014	K141601	Computer-assisted Navigation for Orthopedic Surgery
CTC TCAT(R)-TPLAN(R) 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

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' 3D 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™ (OrthoSense) 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) 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.

Due to the lack of any recent studies on pelvic tumor resection, these sections of the Rationale were removed from this evidence review in 2016.

Literature Review
Evidence reviews 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 patients who are undergoing orthopedic surgery for trauma or fracture.

The question addressed in this evidence review is: Does the use of computer-assisted navigation improve the net health outcome when used for surgery for trauma or fracture?

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

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.

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:

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

Review of Evidence

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,[1,2,3,] only 2 clinical trials 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 3D-computer navigated management (n=24).[5,] Both groups demonstrated 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 patients who are undergoing ligament reconstruction.

The question addressed in this evidence review is: Does the use of computer-assisted navigation improve the net health outcome when used for ligament reconstruction?

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

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:

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

Review of Evidence
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 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 next.

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.[7,] 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).[8,] 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.[9,] 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)[7,]	USA	1	Oct 2014 to Jan 2016	Patients (N = 60) undergoing ACL reconstruction.	CAN (n=30)	Manual placement (n=30)
Hart et al (2008)[8,]	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 (2012)[9,]	Netherlands	1	Jan 2007 to Nov 2009	Patients (N =100) patients ≥18 years of age and eligible for primary ACL reconstruction without additional PCL or lateral collateral ligament injury were included.	CAN (n=49)	Conventional (n=51)
Mauch et al (2007)[10,]	Germany	1	Dec 2003 to 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)[7,]						
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 (n=22 knees)	mean, 1.5 mm at 200 N; p=.49	83%; p=.292	26 (87)	0 (0)		
Hart et al (2008)[8,]						

Study	IKDC	Laxity < 2 mm	Lachman Test (0)	Lachman Test (2+)	Placement of the Femoral Tunnel	Tibial Tunnel Border
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)[9],						
CAN	NR	NR	NR	NR	Mean 39% of the proximal distance on the intracondylar axis	Distance from most medial edge: 42.7% ±3.6%
Manual	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)[10],						
CAN	NR	NR	NR	NR	NR	21.2 mm (32.2%)
Manual	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)[7],	3. Limited demographic information provided.				

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Hart et al (2008)[8],	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)[9],	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)[10],	1, 4.Intended use population is unclear. Limited to athletes			5, 6. Clinically significant difference not prespecified or mentioned.	1,2. Follow-up was 4 days, not 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 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

	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Plaweski et al (2006)[7],		1. Unclear whether patients were blinded.				3. Confidence intervals not reported. 4. Comparison of treatment effect not provided.
Hart et al (2008)[8],	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)[9],						
Mauch et al (2007)[10],	4. Drawing lots is a weak method of allocation.	1, 2, 3. Blinding is not mentioned at all.			1. Power calculations not reported.	3. Confidence intervals not reported.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps 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 patients who are undergoing THA and periacetabular osteotomy.

The question addressed in this evidence review is: Does the use of computer-assisted navigation improve the net health outcome when used for THA and periacetabular osteotomy?

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

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:

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

Review of Evidence

Randomized Controlled Trials

Parratte and Argenson (2007) randomized patients to computer-assisted navigation (n=30) or freehand cup positioning (n=30) for THA by an experienced surgeon.[11,] The mean additional time for the computer-assisted procedure was 12 minutes. There was no difference between the computer-assisted group and the freehand-placement group with regard to the mean abduction or anteversion angles measured by computed tomography. A smaller variation in the positioning of the acetabular component was observed in the computer-assisted navigation group; 20% of cup placements were considered to be outliers in the computer-assisted navigation group compared with 57% in the freehand-placement group.

Lass et al (2014) compared the acetabular component position for computer-assisted navigation and the conventional freehand technique in their randomized trial of 125 patients.[12,] CT scans identified higher accuracy for acetabular component anteversion, less deviation from the target position for anteversion, and fewer outliers from the target for inclination and anteversion. Surgical time was 18 minutes longer for computer-assisted navigation. Functional outcomes were not assessed.

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 Arthoplasty

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 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 patients who are undergoing TKA.

The question addressed in this evidence review is: Does the use of computer-assisted navigation improve the net health outcome when used for TKA?

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

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:

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

Review of Evidence
Systematic Reviews
A systematic review conducted by Xie et al (2012) included 21 randomized trials (N=2 658 patients) that reported on clinical outcomes with or without the use of computer-assisted navigation (Table 6).[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 7).

Rebal et al (2014) conducted a meta-analysis of 20 RCTs (N=1 713 knees) that compared imageless navigation technology with conventional manual guides (Table 6).[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 7). However, these improvements did not achieve the minimal clinically significant difference, defined as a change of 34.5 points.

Table 6. 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 (25-120)	RCT	NR

Study	Dates	Trials	Participants	N (Range)	Design	Duration
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 1 713 knees analyzed	1713 knees (46-166)	RCT	3 mos and 12-32 mos

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

Table 7. Results of Systematic Reviews and Meta-Analyses Investigating Total Knee Arthroplasty

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

CAN: computer-assisted navigation; CI: confidence interval.

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 [20,] 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 [21,] 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 Euroqol 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 Euroqol quality of life questionnaire, and no differences in revision risk.[22,]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.[23,]

Three 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.[24,] 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.[25,] 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.[26,] 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).

Comparative Studies

Results from observational studies have generally been consistent with the systematic reviews and RCTs.[27,-,32,] 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.[31,] 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% confidence interval [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.[32,] 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.[33,] 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.

Computer-Assisted Navigation for Spine Surgery

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 methods, in patients who are undergoing spine surgery, particularly spinal fusion surgery for radiculopathy and correction of spinal deformities (e.g. scoliosis). Spinal fusion may include the use of pedicle screws. Pedicle screws are a type of bone screw that, along with rods, is used to secure the vertebrae in a fixed position following fusion. Pedicle screws may be removed once healing has occurred, or they can be left in place. Pedicle screw placement accuracy is critical, as misplacement can cause a variety of complications, including pain and weakness or perforation leading to damage to surrounding nerves, soft tissues and bones.

The question addressed in this evidence review is: Does the use of computer-assisted navigation improve the net health outcome when used for spine surgery?

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

Populations

The relevant population of interest is individuals who are undergoing spine surgery. This can include patients undergoing cervical, thoracic or lumbar pedicle screw placement in association with spinal fusion surgery, due to trauma or for correction of spinal deformities, or patients undergoing spinal tumor resection.

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 tumor resection and pedicle screw placement.

Comparators

Comparators of interest include conventional/manual surgical methods, such as fluoroscopically-guided freehand surgery.

Outcomes

The general outcomes of interest are symptoms, morbid events, and functional outcomes. Many studies report pedicle screw perforation (breach or encroachment into surrounding tissues, bones or organs) as a measure of procedural success. However, because not all screw perforations lead to symptoms or morbid events, revision surgeries would be a more relevant measure of clinical 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.

Review of Evidence

Pedicle Screw Insertion For Spinal Fusion or Deformity Correction

Randomized Controlled Trials

Three RCTs have compared pedicle screw insertion by computer-assisted navigation with conventional surgical techniques (Table 8). None of the trials reported health outcomes or post-

surgical follow-up (Table 9). In the largest RCT, conducted by Laine et al (2000),[34] computer-assisted navigation was associated with longer surgical time than conventional surgery and fewer instances of pedicle screw perforation. A second, smaller RCT conducted by Rajasekaran et al (2007)[35] found pedicle screw placement using computer-assisted navigation associated with shorter placement time and a lower rate of pedicle perforation relative to fluoroscopically-guided placement. The third trial (N=21) compared the risk of patient and surgical team radiation exposure with pedicle screw placement using computer-assisted navigation with freehand, fluoroscopically-guided screw placement.[36] The trial found significantly higher radiation exposure to the surgical team during freehand screw insertion (p<.01) with no difference between intervention groups and cumulative patient radiation dose. Tables 10 and 11 summarize key study relevance and design and conduct limitations.

Table 8. Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Laine et al (2000)[34]	Finland	1	1998-1999	Patients undergoing thoracolumbar or lumbosacral fusion	Pedicle screw placement using computer-assisted navigation; n=41	Conventional pedicle screw placement; n=50
Rajasekaran et al (2007)[35]	India	1	Not reported	Patients with scoliosis (40°to 80°) or kyphosis (≤90°) undergoing spinal deformity correction of the thoracic spine	Pedicle screw placement using computer-assisted navigation; n=17	Pedicle screw placement using fluoroscopic guidance; n=16
Villard et al (2014)[36]	Germany	1	Not reported	Patients undergoing lower thoracic and lumbar posterior transforaminal interbody fusion	Pedicle screw placement using computer-assisted navigation; n=10	Pedicle screw placement using fluoroscopic guidance as needed; n=11

Table 9. Summary of Key Randomized Controlled Trial Results

Study; Trial	Mean Insertion Time	Pedicle Screw Perforation	Radiation Exposure
Laine et al (2000)[34]	n=91 (496 screws)	n=91 (496 screws)	--
Computer-assisted navigation	40.0 (SD 16) minutes total insertion time	4.6% (10/219)	Not reported
Conventional placement	28.7 (SD 17) minutes total insertion time	13.4% (37/277)	Not reported
p value	p=.001	p=.006	--
Rajasekaran et al (2007)[35]	n=33 (478 screws)	n=33 (478 screws)	--
Computer-assisted navigation	2.4 (SD 0.7) minutes per screw	2.1% (5/242)	Not reported
Conventional placement	4.6 (SD 1.1) minutes per screw	22.9% (54/236)	Not reported
p value	p<.001	p<.001	--
Villard et al (2014)[36]	--	--	n=21 patients
Computer-assisted navigation	Not reported	Not reported	888 (SD 449) cGy•cm^2
Conventional placement	Not reported	Not reported	1884 (SD 881) cGy•cm^2

Study; Trial	Mean Insertion Time	Pedicle Screw Perforation	Radiation Exposure
p value	--	--	p=.73

SD: standard deviation.

Table 10. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Laine et al (2000)[34],				1, 2. The study reported on pedicle screw perforation but not clinical outcomes.	1, 2. Follow-up was insufficient to assess benefits and harms
Rajasekaran et al (2007)[35],				1, 2. The study reported on pedicle screw perforation but not clinical outcomes.	1, 2. Follow-up was insufficient to assess benefits and harms
Villard et al (2014)[36],				1, 2. The study reported on radiation exposure but not clinical outcomes.	1, 2. Follow-up was insufficient to assess benefits and harms

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 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 establish 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 11. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Laine et al (2000)[34],					1. Power calculations not reported	
Rajasekaran et al (2007)[35],					1. Power calculations not reported	
Villard et al (2014)[36],	3. Allocation concealment is unclear	1, 2. Not blinded to treatment assignment or outcome assessment				

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

Systematic Reviews
Numerous systematic reviews of mostly retrospective observational studies have assessed pedicle screw placement using computer-assisted navigation ; however, evidence on health outcomes from the reviews is limited.[37,38,39,40,] In a 2018 review conducted by Staartjes et al, comparing computer-assisted navigation (n=1779 pedicle screws) and freehand placement (n=1809 pedicle screws) and the need for intraoperative revision, there was a nonsignificant trend favoring freehand placement based on an imprecise risk estimate (OR, 1.46 ; 95% CI, 0.30 to 7.17; I^2=88%).[39,] The same review found the need for postoperative revision was significantly lower with computer-assisted navigation versus freehand placement (OR, 0.31 ; 95% CI, 0.21 to 0.46; I^2=0%). Another review, conducted by Perdomo-Pantoja et al (2019)[40,] reported similar rates of screw placement accuracy with computer-assisted navigation (95.5%) and other placement methods (90.5% to 93.1%). Consistent with the RCT evidence discussed above, an older review by Shin et al (2012)[38,] found a lower risk of pedicle screw perforation with computer-assisted navigation (6%; 287/4814) versus conventional, non-navigated screw placement (15%; 556/3725; risk ratio [RR] 0.39 ; 95% CI, 0.31 to 0.49; I^2=49%). The review found no difference between navigated and non-navigated screw placement on operative time (-3.06 minutes ; 95% CI, -35.60 to 29.48), estimated blood loss (-91.6 mL ; 95% CI, -185.95 to 3.24), or overall revision rate per screw insertion (1.44% vs. 2.03%; p=.11)

Other Indications
The use of computer-assisted navigation for the treatment of spinal tumors has been reported in uncontrolled case series and case reports.[41,42,43,] Although the use of computer-assisted navigation appears safe for tumor resection based on these reports, evidence is too limited to draw any conclusions regarding the effect of computer-assisted navigation on health outcomes.

Section Summary - Computer-Assisted Navigation for Spine Surgery
Evidence from RCTs and larger observational studies found that computer-assisted navigation was associated with lower rates of pedicle screw perforation compared with other surgical placement methods. Evidence on clinical outcomes, including long-term health outcomes, is lacking.

Summary of Evidence
For individuals who are undergoing orthopedic surgery for trauma or fracture and receive computer-assisted navigation, the evidence includes 2 retrospective clinical trials, 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 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 older RCTs, a systematic review, 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 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 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 total knee arthroplasty 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.

For individuals who are undergoing spine surgery and receive computer-assisted navigation, the evidence includes RCTs, comparative observational studies, and systematic reviews of those observational studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Computer-assisted navigation for pedicle screw insertion was consistently associated with lower rates of screw perforation relative to other screw insertion methods, but evidence on clinical outcomes such as revision rate is inconsistent or lacking, including long-term outcome follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 3 academic medical centers in 2011. Input was mixed on whether computer-assisted navigation is considered investigational. One reviewer provided additional references on high tibial osteotomy and pelvic tumor resection.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 12.

Table 12. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03628378	Outcomes in Free-hand Versus Sensor-guided Balancing in Total Knee Arthroplasty: a Randomized Controlled Trial	130	Dec 2022
NCT02717299	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
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	210	Apr 2023
Unpublished			
NCT01469299[a]	Prospective Study Measuring Clinical Outcomes of Knee Arthroplasty Using the VERASENSE™ Knee System	285	Dec 2016 (updated 01/11/17)
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

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	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)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/26/2009	New Policy Adoption
08/12/2009	Coding Update
01/06/2012	Policy revision without policy change
09/30/2014	Policy title change from Computer-Assisted Navigation for Orthopedic Surgery Policy revision without policy change
01/01/2017	Policy revision without position change
03/01/2017	Policy title change from Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure Policy revision without position change
06/01/2018	Policy revision without position change
06/01/2019	Policy revision without position change
06/01/2020	Annual review. No change to policy statement. Literature review updated.
06/01/2020	Annual review. No change to policy statement. Literature review updated.
07/01/2021	Annual review. Policy statement, guidelines and literature updated.

Effective Date	Action
06/01/2022	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Computer-Assisted Navigation for Orthopedic Procedure 7.01.96 **Policy Statement:** Computer-assisted surgical navigation for orthopedic procedures is considered **investigational**.	**Computer-Assisted Navigation for Orthopedic Procedures 7.01.96** **Policy Statement:** Computer-assisted surgical navigation for orthopedic procedures is considered **investigational**.