



## FEP Medical Policy Manual

### FEP 7.01.96 Computer-Assisted Navigation for Orthopedic Procedures

**Effective Policy Date:** July 1, 2023

**Original Policy Date:** December 2011

**Related Policies:**

None

## Computer-Assisted Navigation for Orthopedic Procedures

### Description

#### 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.

#### OBJECTIVE

The objective of this evidence review is to determine whether the use of computer-assisted navigation improves the net health outcome when used for orthopedic procedures, including ligament reconstruction, surgery for trauma or fracture, hip arthroplasty, periacetabular osteotomy, total knee arthroplasty, and spine surgery.

#### POLICY STATEMENT

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

## POLICY GUIDELINES

None

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Reimbursement for the technical component of computer-assisted navigation may be sought through the use of the CPT codes listed here or through hospital case rates.

## FDA 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 (eg, 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 (eg, 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
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

### 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.

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

### 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.

#### American Academy of Orthopedic Surgeons

The American Academy of Orthopedic Surgeons updated guidelines in 2022 on surgical management of osteoarthritis of the knee.<sup>44</sup> 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.

#### 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.

## REFERENCES

- Hofstetter R, Slomczykowski M, Krettek C, et al. Computer-assisted fluoroscopy-based reduction of femoral fractures and antetorsion correction. *Comput Aided Surg*. 2000; 5(5): 311-25. PMID 11169877
- Schep NW, Broeders IA, van der Werken C. Computer assisted orthopaedic and trauma surgery. State of the art and future perspectives. *Injury*. May 2003; 34(4): 299-306. PMID 12667784
- Slomczykowski MA, Hofstetter R, Sati M, et al. Novel computer-assisted fluoroscopy system for intraoperative guidance: feasibility study for distal locking of femoral nails. *J Orthop Trauma*. Feb 2001; 15(2): 122-31. PMID 11232651
- Liebergall M, Ben-David D, Weil Y, et al. Computerized navigation for the internal fixation of femoral neck fractures. *J Bone Joint Surg Am*. Aug 2006; 88(8): 1748-54. PMID 16882897
- Swartman B, Pelzer J, Beisemann N, et al. Fracture reduction and screw position after 3D-navigated and conventional fluoroscopy-assisted percutaneous management of acetabular fractures: a retrospective comparative study. *Arch Orthop Trauma Surg*. Apr 2021; 141(4): 593-602. PMID 32519074
- Eggerding V, Reijman M, Scholten RJ, et al. Computer-assisted surgery for knee ligament reconstruction. *Cochrane Database Syst Rev*. Aug 04 2014; (8): CD007601. PMID 25088229
- Plaweski S, Cazal J, Rosell P, et al. Anterior cruciate ligament reconstruction using navigation: a comparative study on 60 patients. *Am J Sports Med*. Apr 2006; 34(4): 542-52. PMID 16556753
- Hart R, Krejzla J, Svoboda P, et al. Outcomes after conventional versus computer-navigated anterior cruciate ligament reconstruction. *Arthroscopy*. May 2008; 24(5): 569-78. PMID 18442690
- Meuffels DE, Reijman M, Verhaar JA. Computer-assisted surgery is not more accurate or precise than conventional arthroscopic ACL reconstruction: a prospective randomized clinical trial. *J Bone Joint Surg Am*. Sep 05 2012; 94(17): 1538-45. PMID 22832975
- Mauch F, Apic G, Becker U, et al. Differences in the placement of the tibial tunnel during reconstruction of the anterior cruciate ligament with and without computer-assisted navigation. *Am J Sports Med*. Nov 2007; 35(11): 1824-32. PMID 17878429
- Kunze KN, Bovonratwet P, Polce EM, et al. Comparison of Surgical Time, Short-term Adverse Events, and Implant Placement Accuracy Between Manual, Robotic-assisted, and Computer-navigated Total Hip Arthroplasty: A Network Meta-analysis of Randomized Controlled Trials. *J Am Acad Orthop Surg Glob Res Rev*. Apr 01 2022; 6(4). PMID 35472191
- Manzotti A, Cerveri P, De Momi E, et al. Does computer-assisted surgery benefit leg length restoration in total hip replacement? Navigation versus conventional freehand. *Int Orthop*. Jan 2011; 35(1): 19-24. PMID 19904533
- Ulrich SD, Bonutti PM, Seyler TM, et al. Outcomes-based evaluations supporting computer-assisted surgery and minimally invasive surgery for total hip arthroplasty. *Expert Rev Med Devices*. Nov 2007; 4(6): 873-83. PMID 18035952
- Reininga IH, Stevens M, Wagenmakers R, et al. Comparison of gait in patients following a computer-navigated minimally invasive anterior approach and a conventional posterolateral approach for total hip arthroplasty: a randomized controlled trial. *J Orthop Res*. Feb 2013; 31(2): 288-94. PMID 22886805
- Hsieh PH, Chang YH, Shih CH. Image-guided periacetabular osteotomy: computer-assisted navigation compared with the conventional technique: a randomized study of 36 patients followed for 2 years. *Acta Orthop*. Aug 2006; 77(4): 591-7. PMID 16929435
- Stiehler M, Goronzy J, Hartmann A, et al. The First SICOT Oral Presentation Award 2011: imageless computer-assisted femoral component positioning in hip resurfacing: a prospective randomised trial. *Int Orthop*. Apr 2013; 37(4): 569-81. PMID 23385606
- Xie C, Liu K, Xiao L, et al. Clinical Outcomes After Computer-assisted Versus Conventional Total Knee Arthroplasty. *Orthopedics*. May 2012; 35(5): e647-53. PMID 22588405
- Rebal BA, Babatunde OM, Lee JH, et al. Imageless computer navigation in total knee arthroplasty provides superior short term functional outcomes: a meta-analysis. *J Arthroplasty*. May 2014; 29(5): 938-44. PMID 24140274
- Blakeney WG, Khan RJ, Palmer JL. Functional outcomes following total knee arthroplasty: a randomised trial comparing computer-assisted surgery with conventional techniques. *Knee*. Mar 2014; 21(2): 364-8. PMID 24703685
- Ltzner J, Dixel J, Kirschner S. No difference between computer-assisted and conventional total knee arthroplasty: five-year results of a prospective randomised study. *Knee Surg Sports Traumatol Arthrosc*. Oct 2013; 21(10): 2241-7. PMID 23851969
- Beyer F, Pape A, Ltznier C, et al. Similar outcomes in computer-assisted and conventional total knee arthroplasty: ten-year results of a prospective randomized study. *BMC Musculoskelet Disord*. Aug 18 2021; 22(1): 707. PMID 34407776
- Cip J, Widemschek M, Luegmair M, et al. Conventional versus computer-assisted technique for total knee arthroplasty: a minimum of 5-year follow-up of 200 patients in a prospective randomized comparative trial. *J Arthroplasty*. Sep 2014; 29(9): 1795-802. PMID 24906519
- Hsu RW, Hsu WH, Shen WJ, et al. Comparison of computer-assisted navigation and conventional instrumentation for bilateral total knee arthroplasty: The outcomes at mid-term follow-up. *Medicine (Baltimore)*. Nov 2019; 98(47): e18083. PMID 31764842
- Song EK, Agrawal PR, Kim SK, et al. A randomized controlled clinical and radiological trial about outcomes of navigation-assisted TKA compared to conventional TKA: long-term follow-up. *Knee Surg Sports Traumatol Arthrosc*. Nov 2016; 24(11): 3381-3386. PMID 26831857
- Cip J, Obwegeser F, Benesch T, et al. Twelve-Year Follow-Up of Navigated Computer-Assisted Versus Conventional Total Knee Arthroplasty: A Prospective Randomized Comparative Trial. *J Arthroplasty*. May 2018; 33(5): 1404-1411. PMID 29426792

26. Farhan-Alanie OM, Altell T, O'Donnell S, et al. No advantage with navigated versus conventional mechanically aligned total knee arthroplasty- 10 year results of a randomised controlled trial. *Knee Surg Sports Traumatol Arthrosc.* Mar 2023; 31(3): 751-759. PMID 36166095
27. Kim YH, Park JW, Kim JS. Computer-navigated versus conventional total knee arthroplasty a prospective randomized trial. *J Bone Joint Surg Am.* Nov 21 2012; 94(22): 2017-24. PMID 23052635
28. Hoppe S, Mainzer JD, Frauchiger L, et al. More accurate component alignment in navigated total knee arthroplasty has no clinical benefit at 5-year follow-up. *Acta Orthop.* Dec 2012; 83(6): 629-33. PMID 23140107
29. Yaffe M, Chan P, Goyal N, et al. Computer-assisted versus manual TKA: no difference in clinical or functional outcomes at 5-year follow-up. *Orthopedics.* May 2013; 36(5): e627-32. PMID 23672916
30. Hoffart HE, Langenstein E, Vasak N. A prospective study comparing the functional outcome of computer-assisted and conventional total knee replacement. *J Bone Joint Surg Br.* Feb 2012; 94(2): 194-9. PMID 22323685
31. Dyrhovden GS, Fenstad AM, Furnes O, et al. Survivorship and relative risk of revision in computer-navigated versus conventional total knee replacement at 8-year follow-up. *Acta Orthop.* Dec 2016; 87(6): 592-599. PMID 27775460
32. Antonios JK, Kang HP, Robertson D, et al. Population-based Survivorship of Computer-navigated Versus Conventional Total Knee Arthroplasty. *J Am Acad Orthop Surg.* Oct 15 2020; 28(20): 857-864. PMID 31934926
33. Webb ML, Hutchison CE, Sloan M, et al. Reduced postoperative morbidity in computer-navigated total knee arthroplasty: A retrospective comparison of 225,123 cases. *Knee.* Jun 2021; 30: 148-156. PMID 33930702
34. Gelalis ID, Paschos NK, Pakos EE, et al. Accuracy of pedicle screw placement: a systematic review of prospective in vivo studies comparing free hand, fluoroscopy guidance and navigation techniques. *Eur Spine J.* Feb 2012; 21(2): 247-55. PMID 21901328
35. Shin BJ, James AR, Njoku IU, et al. Pedicle screw navigation: a systematic review and meta-analysis of perforation risk for computer-navigated versus freehand insertion. *J Neurosurg Spine.* Aug 2012; 17(2): 113-22. PMID 22724594
36. Staartjes VE, Klukowska AM, Schrder ML. Pedicle Screw Revision in Robot-Guided, Navigated, and Freehand Thoracolumbar Instrumentation: A Systematic Review and Meta-Analysis. *World Neurosurg.* Aug 2018; 116: 433-443.e8. PMID 29859354
37. Perdomo-Pantoja A, Ishida W, Zygorakis C, et al. Accuracy of Current Techniques for Placement of Pedicle Screws in the Spine: A Comprehensive Systematic Review and Meta-Analysis of 51,161 Screws. *World Neurosurg.* Jun 2019; 126: 664-678.e3. PMID 30880208
38. Laine T, Lund T, Ylikoski M, et al. Accuracy of pedicle screw insertion with and without computer assistance: a randomised controlled clinical study in 100 consecutive patients. *Eur Spine J.* Jun 2000; 9(3): 235-40. PMID 10905443
39. Rajasekaran S, Vidyadhara S, Ramesh P, et al. Randomized clinical study to compare the accuracy of navigated and non-navigated thoracic pedicle screws in deformity correction surgeries. *Spine (Phila Pa 1976).* Jan 15 2007; 32(2): E56-64. PMID 17224800
40. Villard J, Ryang YM, Demetriades AK, et al. Radiation exposure to the surgeon and the patient during posterior lumbar spinal instrumentation: a prospective randomized comparison of navigated versus non-navigated freehand techniques. *Spine (Phila Pa 1976).* Jun 01 2014; 39(13): 1004-9. PMID 24732833
41. Arand M, Hartwig E, Kinzl L, et al. Spinal navigation in tumor surgery of the thoracic spine: first clinical results. *Clin Orthop Relat Res.* Jun 2002; (399): 211-8. PMID 12011712
42. Van Royen BJ, Baayen JC, Pijpers R, et al. Osteoid osteoma of the spine: a novel technique using combined computer-assisted and gamma probe-guided high-speed intralesional drill excision. *Spine (Phila Pa 1976).* Feb 01 2005; 30(3): 369-73. PMID 15682022
43. Smitherman SM, Tatsui CE, Rao G, et al. Image-guided multilevel vertebral osteotomies for en bloc resection of giant cell tumor of the thoracic spine: case report and description of operative technique. *Eur Spine J.* Jun 2010; 19(6): 1021-8. PMID 20069317
44. American Academy of Orthopaedic Surgeons. Surgical management of osteoarthritis of the knee. 2022. <https://www.orthoguidelines.org/topic?id=1041>. Accessed March 1, 2023.

## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2012	Replace policy	Policy statement changed to "not medically necessary,.
September 2013	Replace policy	Policy updated with literature search; references 6, 9, 14, 16, 19, 21-23,25-27, and 32 added; policy statement unchanged.
March 2017	Replace policy	Policy updated with literature review through November 7, 2016;references 7,12,21,24, 26 and 32 added; some references removed. Title changed to "Computer-Assisted Navigation for Orthopedic Procedure,. Policy statement unchanged except "not medically necessary, corrected to "investigational, due to FDA 510(k) clearance.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; no references added. Policy statement unchanged.
June 2019	Replace policy	Policy updated with literature review through February 4, 2019; references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through February 11, 2020; no references added. Policy statements unchanged
June 2021	Replace policy	Policy updated with literature review through April 3, 2021; references added. Policy statement revised to include spine surgery.
June 2022	Replace policy	Policy updated with literature review through March 3, 2022; references added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through March 1, 2023; references added. Policy statement unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.