



Medical Policy

Computer-Assisted Navigation for Orthopedic Procedure

Table of Contents

- [Policy: Commercial](#)
- [Coding Information](#)
- [Information Pertaining to All Policies](#)
- [Policy: Medicare](#)
- [Description](#)
- [References](#)
- [Authorization Information](#)
- [Policy History](#)

Policy Number: 594

BCBSA Reference Number: 7.01.96 (For Plan internal use only)

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Computer-assisted surgical navigation for orthopedic procedures is considered [INVESTIGATIONAL](#).

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures; image-less
0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image guidance based on fluoroscopic images
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images

Description

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 (eg, 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 (ie, 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 "fiducial 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 were removed from this evidence review in 2016.

Summary

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.

Summary of Evidence

For individuals who are undergoing orthopedic surgery for trauma or fracture and receive computer-assisted navigation, the evidence includes 1 retrospective clinical trial, reviews, and in vitro studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Functional outcomes were not included in the clinical trial, although it did note fewer complications with computer-assisted navigation versus conventional methods. 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 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 total hip arthroplasty 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 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 total knee arthroplasty 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 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.

Policy History

Date	Action
6/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2021	Annual policy review. Policy statement revised to include spine surgery. Effective 10/1/2021
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
6/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2017	Annual policy review. Title changed. New references added. 3/1/2017
8/2015	Annual policy review. New references added.
9/2014	Annual policy review. New references added.
10/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/1/2012	New policy describing ongoing non-coverage. Effective 01/01/2012.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

1. 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
2. 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
3. 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
4. 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
5. 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
6. 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
7. 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
8. Hart R, Krejzla J, Svab P, et al. Outcomes after conventional versus computer-navigated anterior cruciate ligament reconstruction. *Arthroscopy.* May 2008; 24(5): 569-78. PMID 18442690
9. 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
10. 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
11. Parratte S, Argenson JN. Validation and usefulness of a computer-assisted cup-positioning system in total hip arthroplasty. A prospective, randomized, controlled study. *J Bone Joint Surg Am.* Mar 2007; 89(3): 494-9. PMID 17332097
12. Lass R, Kubista B, Olischar B, et al. Total hip arthroplasty using imageless computer-assisted hip navigation: a prospective randomized study. *J Arthroplasty.* Apr 2014; 29(4): 786-91. PMID 24290738
13. 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
14. 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
15. 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
16. 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
17. 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
18. 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
19. 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
20. 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

21. Lutzner 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
22. Beyer F, Pape A, Lutzner 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
23. 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
24. 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
25. 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
26. 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
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. 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
35. 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
36. 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
37. 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
38. 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

39. Staartjes VE, Klukowska AM, Schroder 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
40. Perdomo-Pantoja A, Ishida W, Zygourakis 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
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