

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

Effective Date:	10/1/2023
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[POLICY RATIONALE](#)
[DISCLAIMER](#)
[POLICY HISTORY](#)

[PRODUCT VARIATIONS](#)
[DEFINITIONS](#)
[CODING INFORMATION](#)

[DESCRIPTION/BACKGROUND](#)
[BENEFIT VARIATIONS](#)
[REFERENCES](#)

I. POLICY

Computer assisted surgical navigation for orthopedic procedures is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

[TOP](#)

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

III. DESCRIPTION/BACKGROUND

[TOP](#)

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.

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

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

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 three steps: data acquisition, registration, and tracking.

Data Acquisition

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

Registration

Registration refers to the ability to relate images (i.e., radiographs, computed tomography scans, magnetic resonance imaging, or patients' 3-dimensional anatomy) to the anatomic position in the surgical field. Registration techniques may require the placement of pins or "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.

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

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 onto 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.

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:

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

- 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.	12/2/2019	K191722	Computer-assisted Navigation for Orthopedic Surgery
Stryker Navigation System With Spinemap Go Software Application, Fluoroscopy Trackers, And Fluoroscopy Adapters. Spinemask Tracker	Stryker Corporation	2/14/2019	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

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

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

IV. RATIONALE

[TOP](#)

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 the effects of the technology on net health outcomes.

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 arthroscopy is inconsistent, and more recent RCTs are lacking. The evidence is insufficient to determine the effects of the technology on net health outcomes.

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

For individuals who are undergoing total knee arthroscopy 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 arthroscopy with computer-assisted navigation and total knee arthroscopy 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 the effects of the technology on net health outcomes.

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.

V. DEFINITIONS

[TOP](#)

COMPUTED AXIAL TOMOGRAPHY is a type of imaging that employs basic tomographic technique enhanced by computer imaging. Computer enhancement synthesizes the images obtained from different directions in a given plane, effectively reconstructing a cross-section of the body.

510 (K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

MAGNETIC RESONANCE IMAGING is a type of diagnostic radiography that uses the characteristic behavior of protons (and other atomic nuclei) when placed in powerful magnetic fields to make images of tissues and organs

VI. BENEFIT VARIATIONS

[TOP](#)

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

VII. DISCLAIMER

[TOP](#)

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

[TOP](#)

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

Procedure Codes							
0054T	0055T	20985					

IX. REFERENCES

[TOP](#)

- 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

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

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. 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
12. 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
13. 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
14. 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
15. 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
16. 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
17. 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
18. 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
19. 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
20. 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

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

21. 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
22. 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
23. 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
24. 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
25. 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

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

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, 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
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 randomized 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.
45. Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.96, Computer Assisted Navigation for Orthopedic Procedures. May 2023

X. POLICY HISTORY

[TOP](#)

MP 1.106	CAC 11/30/04
	CAC 10/25/05
	CAC 10/31/06
	CAC 11/27/07
	CAC 7/29/08
	CAC 9/29/09 Consensus review. No change in policy statement. References updated.

MEDICAL POLICY

POLICY TITLE	COMPUTER ASSISTED NAVIGATION FOR ORTHOPEDIC PROCEDURES
POLICY NUMBER	MP- 1.106

	CAC 9/28/10 Consensus review. FEP variation added.
	CAC 10/25/11 Adopt BCBSA guidelines adopted. Previously considered not medically necessary, now considered investigational for orthopedic procedures of the pelvis and appendicular skeleton. Background and references were updated.
	CAC 9/24/13 Consensus review. Medicare is silent project. No change to policy statement. References updated. Rationale Section added. Changed FEP variation to reference MP-7.01.96 Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure in the manual.
	CAC 7/22/14 Consensus review. No change to policy statements. References updated.
	CAC 7/21/15 Consensus review. No change to the policy statement. Codes reviewed.
	2/8/16 Administrative update. New 2016 code added, 0396T
	CAC 7/26/16 Consensus review. No change to the policy statement. Rationale and references updated. Coding reviewed.
	11/23/16 Administrative Update. Variation reformatting.
	CAC 7/25/17 Consensus review. No change to policy statements. References and rationale updated. Added Medicare variation to reference LCD L35094. Title changed to "Computer-Assisted Navigation for Orthopedic Procedure". Formerly Computer Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure. Codes reviewed.
	1/1/18 Administrative update. Medicare variations removed from Commercial Policies.
	4/30/18 Consensus review. Description/Background, Rationale, and Reference sections updated.
	5/7/19 Consensus review. No change to policy statements. Background, summary of evidence, and references updated.
	5/5/20 Consensus review. No change to policy statements. References and summary of evidence updated. Coding reviewed.
	11/18/20 Administrative update. Removed end-dated code 0396T
	3/23/2021 Consensus review. No change to policy statement. Coding reviewed
	05/24/2022 Minor review. Policy statement changed by removing "pelvis and appendicular skeleton". FEP language updated. Background, Rationale, and References revised.
	05/04/2023 Consensus review. No change to policy statement. Background, Rationale and References updated.

[Top](#)

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