

02-20000-30

Original Effective Date: 07/15/04

Reviewed: 06/22/23

Revised: 07/15/23

## Subject: Computer-Assisted Navigation for Orthopedic Procedures

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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### DESCRIPTION:

Computer-assisted navigation (CAN) 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.

CAN devices may be image-based or non-image based. Image-based devices use preoperative computed tomography (CT) 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 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. CAN 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.

Because CAN 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 CAN. (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 received FDA clearance through the 510(k) process with broad labeled indications.

## POSITION STATEMENT:

**Note:** This policy does not address cranial or spinal procedures.

Computer-assisted surgical navigation for orthopedic procedures is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the procedure on health outcomes.

## BILLING/CODING INFORMATION:

### CPT Coding

20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures; image-less (List separately in addition to code for primary procedure) ( <b>Investigational</b> )
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### HCPCS Coding

0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure) ( <b>Investigational</b> )
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) ( <b>Investigational</b> )

## REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage products:** No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

## DEFINITIONS:

No guideline specific definitions apply.

## RELATED GUIDELINES:

[Computer Assisted Surgical Navigation, 02-99221-14](#)

## OTHER:

None Applicable.

## REFERENCES:

1. American Academy of Orthopaedic Surgeons Surgical Management of Osteoarthritis of the Knee Evidence-Based Clinical Practice Guideline. Published December 02, 2022; accessed at [aaos.org](http://aaos.org).
2. Antonios JK, Kang HP, et al. Population-based Survivorship of Computer-navigated Versus Conventional Total Knee Arthroplasty. *J Am Acad Orthop Surg*. 2020 Oct 15;28(20):857-864. PMID: 31934926.
3. Beyer F, Pape A, et al. Similar outcomes in computer-assisted and conventional total knee arthroplasty: ten-year results of a prospective randomized study. *BMC Musculoskelet Disord*. 2021 Aug 18;22(1):707.
4. Biasca N, Wirth S, Bungartz M, Mechanical Accuracy of Navigated Minimally Invasive Total Knee Arthroplasty (MID TKA), 2009 Jan; 16(1): 22-9.
5. Blakeney WG, Khan RJ, Palmer JL. Functional outcomes following total knee arthroplasty: a randomised trial comparing computer-assisted surgery with conventional techniques. *Knee* 2014; 21(2):364-8.
6. Blue Cross Blue Shield Association Evidence Positioning System®; 7.01.96 Computer-Assisted Navigation for Orthopedic Procedure, 05/23.
7. Blue Cross and Blue Shield Association Technology Evaluation Center. Computer-assisted navigation for total knee arthroplasty. *Technology Assessment* Feb 2007;Volume 22:Tab 10.
8. Bohl DD, Nolte MT, et al. Computer-Assisted Navigation Is Associated with Reductions in the Rates of Dislocation and Acetabular Component Revision Following Primary Total Hip Arthroplasty. *J Bone Joint Surg Am*. 2019 Feb 6;101(3):250-256.doi:10.2106/JBJS.18.00108. PMID: 30730484.
9. Christ AB, Pearle AD, et al. Robotic-Assisted Unicompartmental Knee Arthroplasty: State-of-the Art and Review of the Literature. *J Arthroplasty*. 2018 Jul;33(7):1994-2001.
10. Cip J, Obwegeser F, et al. Twelve-Year Follow-Up of Navigated Computer-Assisted Versus Conventional Total Knee Arthroplasty: A Prospective Randomized Comparative Trial. *J Arthroplasty*. 2018 May;33(5):1404-1411. Doi: 10.1016/j.arth.2017.12.012. Epub 2017 Dec 21. PMID: 29426792.
11. Dutton AQ, Yeo SJ, Y KY, et al, Computer-Assisted Minimally Invasive Total Knee Arthroplasty compared with Standard Total Knee Arthroplasty, *The Journal of Bone and Joint Surgery*. 2009 Mar 1; 91 Suppl 2.
12. Gallie PA, et al, Computer-Assisted Navigation for the Assessment of Fixed Flexion in Knee Arthroplasty, *Can J Surg*. 2010 February; 53(1): 42-46.
13. Gausden EB, Popper JE, et al. Computerized Navigation for Total Hip Arthroplasty Is Associated With Lower Complications and Ninety-Day Readmissions: A Nationwide Linked Analysis. *Int Orthop*. 2020 Mar;44(3):471-476. Doi: 10.1007/s00264-019-04475-y. Epub 2020 Jan 9. PMID: 31919568.
14. Gilmour A, MacLean AD, et al. Robotic-Arm-Assisted vs Conventional Unicompartmental Knee Arthroplasty. The 2-Year Clinical Outcomes of a Randomized Controlled Trial. *J Arthroplasty*. 2018 Jul;33(7S):S109-S115.
15. Gothesen O, Espehaug B, Havelin LI et al. Functional outcome and alignment in computer-assisted and conventionally operated total knee replacements: a multicentre parallel-group randomised controlled trial. *Bone Joint J* 2014; 96-B(5):609-18.
16. Hsiue PP, Chen CJ, et al. Trends and Patient Factors Associated With Technology-Assisted Total Hip Arthroplasty in the United States From 2005 to 2014. *Arthroplast Today*. 2020 Mar 9;6(1):112-117.e1. doi: 10.1016/j.artd.2019.12.009. eCollection 2020 Mar. PMID: 32211486.

17. Hsu RW, Hsu WH, et al. Comparison of computer-assisted navigation and conventional instrumentation for bilateral total knee arthroplasty: The outcomes at mid-term follow-up. *Medicine (Baltimore)*. 2019 Nov;98(47):e18083.
18. Jiang L, Chen JY, et al. Clinical outcomes of computer-assisted total knee arthroplasty using pinless navigation. *J Orthop Surg*. 2017 Jan;25(1):2309499016684319.
19. Kamara E, Berliner ZP, et al. Pin Site Complications Associated With Computer-Assisted Navigation in Hip and Knee Arthroplasty. *J Arthroplasty*. 2017 Sep;32(9):2842-2846.
20. Kayani B, Konan S, et al. Robotic-arm assisted total knee arthroplasty has a learning curve of seven cases for integration into the surgical workflow but no learning curve effect for accuracy of implant positioning. *Knee Surg Sports Traumatol Arthrosc*. 2019 Apr;27(4):1132-1141.
21. Khlopas A, Sodhi N, et al. Robotic Arm-Assisted Total Knee Arthroplasty. *J Arthroplasty*. 2018 Jul;33(7):2002-2006.
22. Kim YH, et al. Computer-Assisted Surgical Navigation Does Not Improve the Alignment and Orientation of the Components in Total Knee Arthroplasty. *J Bone Joint Surg Am* 2009; 91(1):2-9.
23. Klasan A, Putnis SE, et al. Conventional Instruments Are More Accurate for Measuring the Depth of the Tibial Cut Than Computer-Assisted Surgery in Total Knee Arthroplasty: A Prospective Study. *Arch Orthop Trauma Surg*. 2020 Mar 7. Doi: 10.1007/s00402-020-03403-9. Online ahead of print. PMID: 32146591.
24. Kleeblad LJ, Borus TA, et al. Midterm Survivorship and Patient Satisfaction of Robotic-Arm-Assisted Medial Unicompartmental Knee Arthroplasty: A Multicenter Study. *J Arthroplasty*. 2018 Jun;33(6):1719-1726.
25. Kunze KN, Bovonratwet P, 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*. 2022 Apr 1;6(4):e21.00200. PMID:35472191.
26. Lass R, Kubista B, Olischar B et al. Total hip arthroplasty using imageless computer-assisted hip navigation: a prospective randomized study. *J Arthroplasty* 2014; 29(4):786-91.
27. Lee DY, Park YJ, et al. No Differences in Mid- To Long-Term Outcomes of Computer-Assisted Navigation Versus Conventional Total Knee Arthroplasty. *Knee Surg Sports Traumatol Arthrosc*. 2019 Nov 29. Doi: 10.1007/s00167-019-05808-5. Online ahead of print. PMID: 31784782.
28. Ly RJ, Koueiter DM, et al. Computer-assisted navigation for intramedullary nail fixation of intertrochanteric femur fractures: A randomized, controlled trial. *Injury*. 2018 Feb;49(2):345-350.
29. Luring C, Beckmann J, Haibock P, et al. Minimal Invasive and computer Assisted Total Knee Replacement Compared with the Conventional Technique: A Prospective, Randomised Trial. *Knee Surg Sports Traumatol Arthrosc*. 2008 Oct; 16(10):928-34.
30. 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* 2013; 21(10):2241-7.
31. Manzotti A, et al. Does Computer-Assisted Surgery Benefit Leg Length Restoration in Total Hip Replacement? Navigation Versus Conventional Freehand. *Int Orthop* 2011; 35(1):19-24.
32. Manzotti A, Pullen C, Confalonieri N, Computer-Assisted Alignment system for Tibial component Placement in Total Knee Replacement: A Radiological Study. *Chir Organi Mov*. 2008 Jan; 91(1): 7-11.
33. Mathew KK, Marchand KB, et al. Computer-Assisted Navigation in Total Knee Arthroplasty. *Surg Technol Int*. 2020 Mar 26;36:sti36/1224. Online ahead of print. PMID: 32294224.

34. Pang CH, et al, Comparison of Total Knee Arthroplasty Using Computer-Assisted Navigation Versus Conventional Guiding Systems: A Prospective Study, Journal of Orthopaedic Surgery 2009; 17(2): 170-3.
35. Parvizi J, Benson JR, Muir JM, A new mini-navigation tool allows accurate component placement during anterior total hip arthroplasty. Med Devices (Auckl). 2018 Mar 22;11:95-104.
36. Pearle AD, Kendoff D, Musahl V, Perspectives on Computer-Assisted Orthopaedic Surgery: Movement Toward Quantitative Orthopaedic Surgery, The Journal of Bone and Joint Surgery (American). 2009; 91: 7-12.
37. Perdomo-Pantoja A, Ishida W, 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. 2019 Jun;126:664-678.e3. doi: 10.1016/j.wneu.2019.02.217. PMID: 30880208.
38. 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 2014; 29(5):938-44.
39. Reininga IH, et al, Minimally Invasive and Computer-Navigated Total Hip Arthroplasty: A Qualitative and Systematic Review of the Literature, BMC Musculoskeletal Disorders 2010, 11:92.
40. Takai H Murayama M, et al, Accuracy analysis of computer-assisted surgery for femoral trochanteric fracture using a fluoroscopic navigation system: Stryker ADAPT® system. Injury. 2018 Mar 19. Pii: S0020-1383(18)30126-8.
41. Tria AJ Jr., Minimally Invasive Total Knee Arthroplasty: Past, Present, and Future, Am J Orthop. 2007 Sep; 36(9 Suppl): 6-7.
42. U.S. Food and Drug Administration (FDA), accessed at fda.gov.

### COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/22/23.

### GUIDELINE UPDATE INFORMATION:

07/15/04	New Medical Coverage Guideline.
01/01/05	HCPCS update; 0055T revision.
07/15/05	Annual review; no change.
06/15/06	Annual review; no change in investigational status.
06/15/07	Annual review; investigational status maintained; reformatted guideline; references updated.
01/01/08	2008 HCPCS update: deleted 0054T, 0055T, and 0056T; Added 20985, 20986, 20987.
07/15/08	Annual review: position statement maintained, Description section and references updated.
01/01/09	Annual HCPCS coding update: added codes 0054T & 0055T; deleted codes 20986 and 20987.
06/15/09	Annual review: position statement maintained and references updated.
11/15/10	Annual review: position statement maintained and references updated.
09/15/11	Scheduled review; position statement maintained and references updated.
10/15/12	Annual review; position statement maintained and references updated.
09/15/13	Annual review; position statement maintained and references updated.

09/15/14	Annual review; position statement maintained, description section and references updated.
10/15/15	Annual review; position statement maintained, references updated.
04/15/17	Revision; Investigational position statement maintained, description section and references updated.
07/15/18	Review; position statement maintained; description and references updated.
08/15/19	Review; position statement maintained and references updated.
06/15/20	Review; Investigational position maintained and references updated.
07/15/21	Review; Position statement, coding, and references updated.
10/15/22	Revision: coding section updated.
07/15/23	Review: Position statement maintained; references updated.