MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Computer-Assisted Navigation for Orthopedic Procedure

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Policy Number: 594

BCBSA Reference Number: 7.01.96
NCD/LCD: Local Coverage Determination (LCD): Category III CPT® Codes (L33392) (A56195)

Related Policies

None

Policy

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

Computer-assisted surgery for orthopedic procedures of the pelvis and appendicular skeleton is considered **INVESTIGATIONAL**.

Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

This is not a covered service.

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link below.

Local Coverage Determinations (LCDs) for National Government Services, Inc.

Local Coverage Determination (LCD): Category III CPT® Codes (L33392) (A56195)

Note: To review the specific LCD, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at https://www.cms.gov for information regarding your specific jurisdiction.

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.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	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.

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

The goal of computer-assisted navigation (CAN) is to increase surgical accuracy and reduce the chance of malposition. For total knee arthroplasty (TKA), 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, risk of osteolysis, and loosening of the prosthesis. In addition to reducing the risk of substantial malalignment, CAN may improve soft tissue balance and patellar tracking. CAN 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 CAN for surgical procedures of the appendicular skeleton include screw placement for fixation of femoral neck fractures, high tibial osteotomy, and tunnel alignment during reconstruction of the anterior cruciate ligament.

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 TKA, 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 movement of the thigh through a series of circular arcs, with the computer producing a 3-dimensional (3D) 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.

Navigation involves 3 steps: data acquisition, registration, and tracking.

Data Acquisition
Data can be acquired in 3 ways: fluoroscopically, guided by CT scan or magnetic resonance imaging (MRI), or guided by imageless systems. These data are then used for registration and tracking.

Registration
Registration refers to the ability of relating images (ie, radiographs, CT scans, MRI, 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 with respect to the bony anatomy of interest.

VERASENSE (OrthoSense) is a single-use device that replaces the standard plastic tibial trial spacer used in TKA. 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 on 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 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.

Summary

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.

For individuals who are undergoing orthopedic surgery for trauma or fracture, ligament reconstruction, hip arthroplasty and periacetabular osteotomy, or total knee arthroplasty who receive CAN, the evidence includes randomized controlled trials (RCTs) and nonrandomized comparative studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Overall, the literature supports a decrease in variability of alignment with CAN, particularly with respect to the number of outliers. Although some observational data have suggested that malalignment may increase the probability of early failure, recent RCTs with short- to mid-term follow-up have not shown improved clinical outcomes with CAN. Given the low short-term revision rates associated with conventional procedures and the inadequate power of the available studies to detect changes in function using CAN, studies are needed that assess health outcomes using CAN in a larger number of subjects with longer follow-up to permit greater certainty on the impact of this technology. The evidence is insufficient to determine the effects of the procedure on health outcomes.

Policy History

Date	Action
3/2017	BCBSA National medical policy review. Title changed. New references added. 3/1/2017
8/2015	New references added from BCBSA National medical policy.
9/2014	New references added from BCBSA National medical policy.
10/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/1/2012	New policy, effective 01/01/2012, describing ongoing non-coverage.

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):311-325. 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):122-131. PMID 11232651
4. Suhm N, Jacob AL, Nolte LP, et al. Surgical navigation based on fluoroscopy--clinical application for computer-assisted distal locking of intramedullary implants. Comput Aided Surg. 2000;5(6):391-400. PMID 11295852
5. 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):1748-1754. PMID 16882897
6. Eggerding V, Reijman M, Scholten RJ, et al. Computer-assisted surgery for knee ligament reconstruction. Cochrane Database Syst Rev. 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):542-552. 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):569-578. 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 5 2012;94(17):1538-1545. 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):1824-1832. 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):494-499. 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):786-791. 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):873-883. 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):288-294. 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):591-597. 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):569-581. PMID 23385606
18. Blue Cross and Blue Shield Association Technology Evaluation Center. Computer-assisted navigation for total knee arthroplasty. Technology Assessment Feb 2007;Volume 22:Tab 10. PMID 18411501
19. Xie C, Liu K, Xiao L, et al. Clinical outcomes after computer-assisted versus conventional total knee arthroplasty. Orthopedics. May 1 2012;35(5):e647-653. PMID 22588405
20. 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):938-944. PMID 24140274
21. 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. May 2014;96-B(5):609-618. PMID 24788494
22. Blyth MJ, Smith JR, Anthony IC, et al. Electromagnetic navigation in total knee arthroplasty-a single center, randomized, single-blind study comparing the results with conventional techniques. J Arthroplasty. Feb 2015;30(2):199-205. PMID 25263246
23. 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):364-368. PMID 24703685
24. Lutzner J, Dexel 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):2241-2247. PMID 23851969
25. 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):1795-1802. PMID 24906519
26. 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
27. Kim YH, Kim JS, Choi Y, 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. Jan 2009;91(1):14-19. PMID 19122074
28. 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):2017-2024. PMID 23052635
29. 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):629-633. PMID 23140107
30. 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 1 2013;36(5):e627-632. PMID 23672916
31. 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):194-199. PMID 22323685
32. 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