BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Computer-Assisted Navigation for Orthopedic Procedure

Policy #: 229
Category: Surgery

Latest Review Date: July 2021
Policy Grade: B

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after March 24, 2020:

Blue Advantage will treat **computer-assisted surgical navigation** when used as an adjunct to orthopedic procedures, including but not limited to the pelvis and appendicular skeleton as a **non-covered** benefit and as **investigational**.

Effective for dates of service February 26, 2018 through March 23, 2020, refer to LCDs L34555 & L36954.

Effective for dates of service prior to February 26, 2018:

Blue Advantage will treat **Computer-assisted surgical navigation,** when used as an adjunct to orthopedic procedures including but not limited to the pelvis and appendicular skeleton, as a **non-covered** benefit and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

Computer-Assisted Navigation

The goal of CAN is to increase surgical accuracy and reduce the chance of malposition. For total knee arthroplasty (TKA), malalignment is commonly defined as variation of greater than three degrees 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, computer navigation may improve soft tissue balance and patellar tracking. CAN is also being investigated for operations with limited visibility such as placement of the acetabular cup in total hip arthroplasty (THA), 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 (ACL).

Computer-assisted navigation devices may be image-based or non-image based. Image-based devices use preoperative 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 (e.g., infrared) detect the reflected signals and transmit the data to a dedicated computer. During the surgical procedure, 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 three-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.

Navigation involves three steps described below: data acquisition, registration, and tracking.

- Data Acquisition
    - Data can be acquired in three different ways: fluoroscopically, CT/MRI-guided, or imageless systems. This data is then used for registration and tracking.
- Registration
    - Registration refers to the ability of relating images (i.e., x-rays, CT, MRI, or patients' 3-D anatomy) to the anatomical 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 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 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 can then provide real time information on the position and orientation of the tools' alignment with respect to the bony anatomy of interest.

The 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 the 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 relationship 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.

KEY POINTS:

The policy has been updated regularly using the MEDLINE database. The most recent literature update was performed through April 3, 2021.

Summary of Evidence

For individuals who are undergoing orthopedic surgery for trauma or fracture and receive computer-assisted navigation, the evidence includes one 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 CAN versus conventional methods. The evidence is insufficient to determine the effects of the technology on net health outcomes.

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 CAN 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 CAN, and no trials looked at functional

outcomes or need for revision surgery with CAN. 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 older RCTs, a systematic review, and comparison studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Evidence on the relative benefits of CAN 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.

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 (TKA) with CAN and TKA without CAN is increased surgical time with CAN. Few differences in clinical and functional outcomes were seen at up to 10 years postprocedure. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventative Service Task Force Recommendations
Not applicable.

KEY WORDS:

Computer-assisted navigation (CAN), total hip arthroplasty (THA), total knee arthroplasty (TKA), anterior cruciate ligament (ACL), computer-assisted minimally invasive total knee arthroplasty, periacetabular osteotomy, surgical-navigation system, VERASENSE™ Knee System, iASSIST™ Knee, NuVasive Pulse System, NuVasive Next Generation NVM5 System, JointPoint, Exactech GPS, Verasense Knee System, IAssist Knee System, CTC TCAT®-TPLAN® Surgical System, Digimatch orthodoc Robodoc Encore Surgical System.

APPROVED BY GOVERNING BODIES:

Because computer-assisted navigation is a surgical navigation 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) clearance from FDA. As such, the FDA does not require data documenting the intermediate or final health outcomes associated with computer-assisted surgery. (In contrast, robotic procedures, in which the actual surgery is robotically performed, are subject to the more rigorous requirement of the PMA process.)

A variety of surgical navigation procedures have been cleared for marketing by 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 have received FDA clearance specifically for total knee arthroplasty. These include the PiGalileo™ Computer-Assisted Orthopedic Surgery System, PLUS Orthopedics; OrthoPilot® Navigation System, Braun; Navitrack® Navigation System, and ORTHO soft. 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 utilized to place surgical instruments during surgery utilizing anatomical landmarks and other data specifically obtained intra-operatively (e.g., ligament tension, limb alignment, etc). 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"

In 2013, the VERASENSE™ Knee System from OrthoSensor™ and the iAssist™ Knee from Zimmer received 510(k) clearance from FDA.

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.	12/02/201919	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

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image guidance based on fluoroscopic images (list separately in addition to code for primary procedure)
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure with image guidance based on CT and MRI images (list separately in addition to code for primary procedure)
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (list separately in addition to code for primary procedure)

PREVIOUS CODING:

0396T	Intra-operative use of kinetic balance sensor for implant stability during knee replacement arthroplasty (list separately in addition to code for primary procedure) (Deleted 12/31/20)

REFERENCES:

1. Antonios JK, Kang HP, Robertson D, et al. Population-based Survivorship of Computer-navigated Versus Conventional TotalKnee Arthroplasty. J Am Acad Orthop Surg. Oct 15 2020; 28(20): 857-864.
2. 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):364-368.
3. 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. 2018 May;33(5):1404-1411.
4. 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.
5. 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 2016l 87(6):592-599.
6. Eggerding V, Reijman M, Scholten RJ, et al. Computer-assisted surgery for knee ligament reconstruction. Cochrane Database Syst Rev. 2014; 8:CD007601.
7. Hart R, Krejzla J, Svab P et al. Outcomes after conventional versus computer-navigated anterior cruciate ligament reconstruction. Arthroscopy 2008; 24(5):569-578.
8. 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 2012; 94(2):194-199.
9. Hofstetter R, et al. Computer-assisted fluoroscopy-based reduction of femoral fractures and antetorsion. Computer Aided Surgery, January 2000; 5(5): 311-325.
10. 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 2012; 83(6):629-633.
11. Hsieh PH, et al. Image-guided periacetabular osteotomy: computer-assisted navigation compared with the conventional technique: A randomized study of 36 patients followed for 2 years. Acta Orthopedics, August 2006; 77(4): 591-597.
12. Hsu RW, Hsu WH, Shen WJ, et al. Comparison of computer-assisted navigation and conventional instrumentation for bilateraltotal knee arthroplasty: The outcomes at mid-term follow-up. Medicine (Baltimore). Nov 2019; 98(47): e18083.
13. Kim YH, Park JW, Kim JS. Computer-navigated versus conventional total knee arthroplasty a prospective randomized trial. J Bone Joint Surg Am 2012; 94(22):2017-2024.
14. 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):786-791.
15. Liebergall M, et al. Computerized navigation for the internal fixation of femoral neck fractures. American Journal Bone Joint Surgery. August 2006; 88(8): 1748-1754.

16. 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 2013; 21(10):2241-2247.
17. 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 2011; 35(1):19-24.
18. Mauch F, Apic G, Becker U and Bauer G. 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, November 2007; 35(11): 1824-1832.
19. 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 2012; 94(17):1538-1545.
20. Parratte S, et al. Validation and usefulness of a computer-assisted cup-positioning system in total hip arthroplasty. A prospective, randomized, controlled study. American Journal Bone Joint Surgery, March 2007; 89(3): 494-499.
21. .
22. Plaweski S, et al. Anterior cruciate ligament reconstruction using navigation: A comparative study on 60 patients. American Journal Sports Medicine, April 2006; 34(4): 542-552.
23. 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):938-944.
24. 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 2013; 31(2):288-294.
25. Schep NW, et al. Computer-assisted orthopedic and trauma surgery. State of the art and future perspectives. Injury, May 2003; 34(4): 299-306.
26. Slomczykowski, MA, et al. Novel computer-assisted fluoroscopy system for intraoperative guidance: Feasibility study for distal locking of femoral nails. Journal of Orthopaedic Trauma, February 2001; 15(2): 122-131.
27. 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.
28. 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 2013; 37(4):569-581.
29. 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, November 2007; 4(6): 873-883.
30. Xie C, Liu K, Xiao L et al. Clinical outcomes after computer-assisted versus conventional total knee arthroplasty. Orthopedics 2012; 35(5):e647-653.

31. 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 2013; 36(5):e627-632.

POLICY HISTORY:

Adopted for Blue Advantage, August 2005
Available for comment August 30-October 13, 2005
Medical Policy Group, June 2007
Medical Policy Group, February 2008
Medical Policy Group, February 2010
Medical Policy Group, May 2011
Medical Policy Group, July 2012
Medical Policy Group, July 2013
Medical Policy Group, July 2014
Medical Policy Group, July 2015
Medical Policy Group, December 2015
Medical Policy Group, December 2016
Medical Policy Group, January 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
Medical Policy Group, October 2020: Annual Coding Update. Moved CPT 0396T from Current coding section. Created Previous Coding section to include code 0396T.
Medical Policy Group, July 2021
