

***Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.***



**BlueCross BlueShield  
of Alabama**

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**Name of Blue Advantage Policy:**  
**Computer-Assisted Navigation for Orthopedic Procedure**

Policy #: 229

Latest Review Date: April 2023

Category: Surgery

**ARCHIVED EFFECTIVE 11/1/2023**

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**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:**

**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 computer-assisted navigation 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. Computer-assisted navigation 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 "fiducial 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 March 1, 2023.

### **Summary of Evidence**

For individuals who are undergoing orthopedic surgery for trauma or fracture and receive computer-assisted navigation, the evidence includes two 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 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 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.

For individuals who are undergoing total knee arthroscopy (TKA) 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 TKA 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 postprocedure. 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.

## **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**

<b>Device</b>	<b>Manufacturer</b>	<b>Date Cleared</b>	<b>510(k) No.</b>	<b>Indication</b>
Vital Navigation System	Zimmer Biomet Spine, Inc.	12/02/2019	K191722	Computer-assisted Navigation for Orthopedic Surgery
Stryker Navigation System With Spinemap Go Software Application, Fluoroscopy Trackers And Fluoroscopy Adapters. Spinemask Tracker	Stryker Corporation	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)
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## **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

Medical Policy Group, May 2022

Medical Policy Group, April 2023

Medical Policy Group, November 2023: Archived effective 11/1/2023.

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*