

Corporate Medical Policy

Computer Assisted Surgical Navigational Orthopedic Procedures

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

Background

The goal of CAN is to increase surgical accuracy and reduce the chance of malposition of implants. For total knee arthroplasty (TKA), malalignment is commonly defined as a variation of greater than 3 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, 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 for 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 (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 (3-D) 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.

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I. Data Acquisition

Data can be acquired by fluoroscopy, CT/MRI, or imageless systems, allowing for preoperative and intraoperative planning. This data is then used for registration and tracking.

II. 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. This requires an additional surgical procedure. 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.

III. 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 can then provide real time information of 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.

Regulatory Status

Surgical navigation systems require U.S. Food and Drug Administration (FDA) clearance, but generally are subject only to 510(k) clearance since computer assisted surgery is considered analogous to a surgical information system in which the surgeon is only acting on the information that is provided by the navigation system. As such, the FDA does not require data documenting the intermediate or final health outcomes associated with computer assisted surgery.

A variety of surgical navigation procedures have received FDA clearance through the 510(k) process with broad labeled indications. The following is an example; "The OEC FluoroTrak 9800 Plus provides the physician with fluoroscopic imaging during diagnostic, surgical, and interventional procedures. The surgical navigation feature is intended as an aid to the surgeon for locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic

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surgery and which provides a reference to rigid anatomical structures such as sinus, skull, long bone or vertebra visible on fluoroscopic images.”

Several navigation systems (e.g., PiGalileo™ Computer-Assisted Orthopedic Surgery System, PLUS Orthopedics; OrthoPilot® Navigation System, Braun; Navitrack® Navigation System, ORTHOsoft) have received FDA clearance specifically for TKA. 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 intra-operatively (e.g., ligament tension, limb alignment). 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 the FDA.

Other computer-assisted navigation devices cleared by FDA include, but are not limited to:

- Vital Navigation System (Zimmer Biomet Spine, Inc.)
- Stryker Navigation System (Stryker Corporation)
- NuVasive Pulse System (NuVasive Inc.)
- VERASENSE for Zimmer Biomet Persona (OrthoSensor)
- NuVasive Next Generation (NuVasive Inc.)
- Stryker OrthoMap Versatile Hip System (Stryker Corporation)
- JointPoint (JointPoint Inc.)
- Exactech GPS (Blue Ortho)

RELATED POLICIES

Patient Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty
Three Dimensional Printed Orthopedic Implants

****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

Policy

Computer Assisted Surgical Navigational Orthopedic Procedures of the pelvis and appendicular skeleton are considered investigational. BCBSNC does not provide coverage for investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Computer Assisted Surgical Navigational Orthopedic Procedures are covered

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Not applicable.

When Computer Assisted Surgical Navigational Orthopedic Procedures are not covered

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

Policy Guidelines

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 computer-assisted navigation 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 five 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 older RCTs, a systematic review, 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 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 ten years post-procedure. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbnsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 20985, 0054T, 0055T, 0396T

Codes are intended to be used in addition to the code for the primary procedure.

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BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 2/25/04

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 4/25/06

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Specialty Matched Consultant Advisory Panel review 7/2011

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Specialty Matched Consultant Advisory Panel review 7/2012

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Medical Director review 7/2013

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Burnett RS, Barrack RL. Computer-assisted total knee arthroplasty is currently of no proven clinical benefit: a systematic review. *Clin Orthop Relat Res.* 2013 Jan;471(1):264-76

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):629-33.

Medical Director review 7/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 7/10/14

Specialty Matched Consultant Advisory Panel review 7/2014

Specialty Matched Consultant Advisory Panel review 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 7/9/15

Specialty Matched Consultant Advisory Panel 6/2016

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Specialty Matched Consultant Advisory Panel 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 4/12/2018

Specialty Matched Consultant Advisory Panel 6/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 4/8/2019

Specialty Matched Consultant Advisory Panel 7/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 4/16/2020

Specialty Matched Consultant Advisory Panel 6/2020

Policy Implementation/Update Information

- 10/28/04 New Policy issued. Computer-assisted surgical navigational orthopedic procedures are considered investigational. Reference added.
- 6/2/2005 Specialty Matched Consultant Advisory Panel review on 5/23/2005. Policy statement revised to include phrase (noted in []) that computer assisted navigational orthopedic procedures [of the pelvis and appendicular skeleton] are considered investigational and not covered. No other changes made. Reference added.
- 6/18/07 References updated. Specialty Matched Consultant Advisory Panel review 5/18/07. No changes to policy coverage criteria. (adn)

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- 12/31/07 Coding Update. CPT Codes 0054T, 0055T and 0056T have been replaced with 20985, 20986, 20987. (adn)
- 01/05/09 CPT codes 20986 and 20987 deleted. Added codes 0054T and 0055T. (adn)
- 7/6/09 Description section revised for clarity. Rationale regarding investigational status added to Policy Guidelines section. References updated. Specialty Matched Consultant Advisory Panel review meeting 5/21/09. No change to policy statement. (adn)
- 8/17/10 Specialty Matched Consultant Advisory Panel review 7/2010. Removed Medical Policy number. Updated references. Updated Description section. (mco)
- 8/16/11 Specialty Matched Consultant Advisory Panel review 7/2011. Updated "Description" section to include two new potential uses for Computer Assisted Surgical Navigation; high tibial osteotomy and pelvic tumor resection. Procedure remains investigational. References updated. (mco)
- 8/7/12 Specialty Matched Consultant Advisory Panel review 7/2011. References updated. Policy Guidelines updated. No changes to Policy Statement. (mco)
- 8/13/13 Specialty Matched Consultant Advisory Panel review 7/2013. References updated. Medical Director review 7/2013. (mco)
- 8/12/14 Description section updated to include FDA approved products. Specialty Matched Consultant Advisory Panel review 7/2014. References updated. Medical Director review 7/2014. (mco)
- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. (sk)
- 9/1/15 Reference added. (sk)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. (sk)
- 4/28/17 Reference added. Policy Guidelines updated. Code 0396T added to Billing/Coding section. (sk)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. (sk)
- 7/13/18 Reference added. Specialty Matched Consultant Advisory Panel review 6/27/2018. Related policies added. (sk)
- 9/10/19 Reference added. Specialty Matched Consultant Advisory Panel review 7/30/2019. (sk)
- 6/30/20 Reference added. List of FDA approved devices added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/17/2020. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.
