

## Corporate Medical Policy

### Computer Assisted Surgical Navigational Orthopedic Procedures

**File Name:** computer\_assisted\_surgical\_navigational\_orthopedic\_procedures  
**Origination:** 10/2004  
**Last CAP Review:** 7/2011  
**Next CAP Review:** 7/2012  
**Last Review:** 7/2011

#### Description of Procedure or Service

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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, 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 operations 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.

##### I. Data Acquisition

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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, described below. Image guided systems are somewhat self explanatory. The image-less systems rely on other information such as centers of rotation of the hip knee, or ankle, or visual information like anatomical landmarks.

## 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 "fiduciary 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.

Surgical navigation systems require 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 navigational procedures have received FDA clearance through the 510(k), and in general the labeled indications are very broad.

***\*\*\*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

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

## Benefits Application

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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

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BCBSNC does not provide coverage for Computer Assisted Surgical Navigational Orthopedic

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## Policy Guidelines

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The literature supports a decrease in variability of alignment with computer-assisted navigation, particularly with respect to the number of outliers. Although some observational data suggest that malalignment may increase the probability of early failure, recent randomized, controlled trials with short to mid-term follow-up have not shown improved health outcomes. Given the low short-term revision rates associated with conventional procedures and the inadequate power of available studies to detect changes in function, studies that assess health outcomes in a larger number of subjects with longer follow-up are needed. The most promising utilization of this procedure appears to be the ability to decrease incision length without loss of accuracy in component alignment. Another area of potential benefit is pelvic tumor resection. Evidence at this time has not adequately demonstrated improved health outcomes with this more resource-intensive combination. Continued technology development in this area is expected.

## Billing/Coding/Physician Documentation Information

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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.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

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

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

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

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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

Ontario Health Technology Advisory Committee (OHTAC) Ministry of Health and Long-term Care. Medical Advisory Secretariat (March 2004). Computer assisted Hip and Knee Arthroplasty: navigation and robotic systems. Retrieved 2/15/07 from [http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/sum\\_arthro\\_020104.html](http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/sum_arthro_020104.html)

Centers for Medicare and Medicaid Services. Summary report: ICD-9-CM Coordination and Maintenance Committee (April 2004). Computer-assisted Surgery (CAS). Retrieved 2/15/07 from <http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/Downloads/icd040104.pdf>

Ulrich SC, Bonutti PM, Seyler RM, Marker DR, Jones LC, Mont MA. Outcomes-based evaluations supporting computer-assisted surgery and minimally invasive surgery for total hip arthroplasty. *Expert Rev Med Devices* 2007; 4(6): 873-883

BCBSA TEC Assessment [Electronic Version]. 2007

# Computer Assisted Surgical Navigational Orthopedic Procedures

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 1/8/09

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* 2009; 91(1):14-19

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 02/11/10

Specialty Matched Consultant Advisory Panel review 7/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 5/12/11

Specialty Matched Consultant Advisory Panel review 7/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.96, 7/14/11

## Policy Implementation/Update Information

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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)

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)

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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.