



Corporate Medical Policy

Computer Assisted Surgical Navigational Orthopedic Procedures

File Name: computer_assisted_surgical_navigational_orthopedic_procedures
Policy Number: SUR6165
Origination: 10/2004
Last CAP Review: 5/2009
Next CAP Review: 5/2011
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Description of Procedure or Service

The term "computer assisted musculoskeletal surgical navigational orthopedic procedure" describes navigational systems that provide additional information during a procedure that attempts to further integrate preoperative planning with intraoperative execution. The proposed advantages include: an increase in accuracy to reduce the chance of malposition of implants, less invasive operations, better planning and simulations, and reduction of radiation exposure.

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

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, 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 "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.

Surgical navigations 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.

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Policy

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

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

When Computer Assisted Surgical Navigational Orthopedic Procedures are covered

Not applicable.

When Computer Assisted Surgical Navigational Orthopedic Procedures are not covered

BCBSNC does not provide coverage for Computer Assisted Surgical Navigational Orthopedic Procedures. It is considered investigational. BCBSNC does not provide coverage for investigational services.

Policy Guidelines

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. 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.

A 2007 BCBSA TEC Assessment evaluated computer-assisted navigation for total knee replacement. The report concluded that no direct evidence is currently available to support an improvement in clinical outcomes with computer-assisted navigation for total knee arthroplasty. As a result of deficiencies in the available evidence (e.g., potential for bias in observational studies and lack of long-term follow-up in the randomized clinical trials), it is not possible to determine whether the degree of improvement in alignment that has been reported leads to meaningful improvements in clinically relevant outcomes such as pain, function, or revision surgery. Therefore, the use of computer-assisted navigation for total knee arthroplasty did not meet TEC criteria.

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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.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

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

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

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

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)

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)

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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)

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.