MEDICAL POLICY

SUBJECT: COMPUTER ASSISTED NAVIGATION FOR KNEE AND HIP ARTHROPLASTY

POLICY NUMBER: 7.01.67
CATEGORY: Technology Assessment

EFFECTIVE DATE: 03/17/05
REVISED DATE: 01/19/06, 12/21/06, 11/15/07, 10/23/08, 09/17/09
ARCHIVED DATE: 09/16/10
EDITED DATE: 08/18/11, 08/16/12, 08/15/13, 08/21/14, 08/20/15, 08/18/16, 08/17/27

If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.

If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.

If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT:

Based upon our criteria and assessment of the peer-reviewed literature, neither computer assisted hip or knee arthroplasty, improve patient outcomes over existing techniques, and therefore, are considered not medically necessary.

POLICY GUIDELINES:

I. Computer navigation technology is an adjunct to joint arthroplasty and coverage for the arthroplasty is not affected by the not medically necessary status of computer navigation devices.

II. Robotic devices are not addressed in this medical policy.

DESCRIPTION:

Computer assisted orthopedic surgery describes navigation systems that provide additional information during a procedure to further integrate preoperative planning with intraoperative execution. The goal of using navigation systems in joint arthroplasty is to improve positioning of prosthesis components. Malalignment of prosthetic components contributes to loosening and instability of the joint. Navigation involves three steps: data acquisition, registration, and tracking. Data can be acquired in three different ways; from fluoroscopic, CT/MRI guided, or imageless systems. (Imageless systems rely on information such as centers of rotation of the hip, knee, or ankle, or visual information like anatomical landmarks.) The data is then used for registration and tracking. Registration refers to relating images (e.g., x-rays, CT, MRI or patients’ 3-D anatomy) to the anatomical position in the surgical field. Tracking refers to the sensors and measurement devices that can provide feedback during surgery regarding the orientation and position of instruments and implants relative to bone anatomy.

RATIONALE:

The FDA has granted 510(k) status to a number of surgical navigation systems including, but not limited to, Aesculap’s Orthopilot® Navigation Platform; PiGalileo™ Computer-Assisted Orthopedic Surgery System, (PLUS Orthopedics); OrthoPilot® Navigation System, (Braun); Biomet’s Signature system; and the Navitrack® Navigation System, (ORTHOsoft). The FDA does not require data documenting the intermediate or final health outcomes associated with 510(k) status.

Studies have concluded that computer-assisted navigation resulted in more accurate alignments than conventional surgeries for the femur in total knee arthroplasties, improved frontal and sagittal alignment of the femoral component in total knee arthroplasty, and can improve acetabular cup positioning in total hip arthroplasty. However, the studies have also concluded that the technology offers only a small amount of additional benefit to patients, and is often unnecessary when an experienced surgeon performs surgery. There is no evidence that demonstrates that the use of computer-assisted navigation provides an overall health benefit to patients undergoing total knee or hip arthroplasties (e.g., decreased instability, reoperation).
Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN).

**CPT:**
- 20985 (NMN) Computer-assisted surgical navigational procedure for musculoskeletal procedures; image-less (List separately in addition to code for primary procedure)
- 0054T (NMN) Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image guidance based on fluoroscopic images (List separately in addition to code for primary procedure)
- 0055T (NMN) Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image guidance based on CT/MRI images (List separately in addition to code for primary procedure)

**REFERENCES:**


*key article

**KEY WORDS:**

Computer assisted orthopedic surgery, Image guided orthopedic surgery.
There is currently a Local Coverage Determination (LCD) addressing Category III CPT codes that includes computer-assisted musculoskeletal surgical navigational orthopedic procedures. Please refer to the following LCD website for Medicare Members:

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ContrId=298&ver=36&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&name=National+Governme nt+Services%2c+Inc.+%(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAIAAAAAA%3d%3d#0.