CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Computer-Assisted Surgical Navigation for Musculoskeletal Procedures, Including Spinal**

Effective Date **6/15/2010**
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Coverage Policy

CIGNA does not cover the adjunctive use of computer assisted navigation during musculoskeletal surgical procedures, including spinal, because it is considered experimental, investigational or unproven.

General Background

Computer-assisted surgery (CAS), or computer-assisted navigation system, refers to an evolving technology of computerized systems that provide additional information during surgical procedures. The proposed advantages of computer-assisted orthopedic surgery include: an increase in accuracy, less invasive operations, better planning and simulation, and reduction of radiation exposure for both patient and surgeon (Schep, et al., 2003).

As an emerging technology, CAS was initially proposed for preoperative planning and to improve accuracy during neurosurgery to improve intracranial needle biopsies, isotope implantation and tumor resection. Computer-assisted surgery has also been utilized during cardiology and endoscopic surgery. Some surgeons have extended the application to musculoskeletal and/or spinal procedures, for example, placement of lumbar pedicle screws for treatment of scoliosis, spondylolisthesis, fractures and instability, and for procedures such as total hip arthroplasty, periacetabular osteotomy, total knee arthroplasty and knee ligament surgery.

CAS is often used during joint arthroplasty procedures and a majority of the published evidence focuses on total knee replacement. In general, when used as an adjunct to joint replacement surgeries, computer-assisted surgery may improve positioning of prosthetic components, preventing misalignment. In addition, computerized assistance has been utilized during minimally invasive surgical techniques; which have also been associated with difficulties in prosthetic alignment and positioning. Misalignment of components is a leading cause of instability and reoperation for both hip and knee replacement. Computer assistance provides the surgeon with instant information and feedback, which authors hypothesize can allow for more accurate decision-making during the procedure.

Computer-assisted navigation generally involves three steps: planning (i.e., data acquisition), navigation (i.e., tracking) and registration. Data (i.e., preoperative or intraoperative images) can be acquired by fluoroscopy, computerized tomography (CT) scans or magnetic resonance imaging (MRI), or by way of imageless systems, allowing for preoperative and intraoperative planning. Images and data are updated in real time throughout the surgical procedure allowing for intraoperative feedback to the surgeon. The system generates a digital map of the patient's anatomy. Integrating surgical instrumentation allows the surgeon to navigate the instruments relative to the patient's map during the procedure (Swank and Lehnert, 2005).

Standard surgical techniques for joint replacement currently utilize mechanical intramedullary or extramedullary guiding systems; computer-assisted navigation is proposed as an adjunct to conventional arthroplasty or as an alternative to existing fluoroscopic image guidance. For other procedures such as anterior cruciate ligament reconstruction and osteochondral grafting, guiding systems are not routinely used and placement is manual.

U.S. Food and Drug Administration (FDA)
Several surgical navigation systems have received FDA clearance through the 510(k) process as stereotaxic instruments, some of which include Surgetics Ortho Kneelogic Navigation System (Praxim, Medical Device Consultants, Inc., North Attleboro, MA); DePuy CAS Knee Instrumentation (DePuy Orthopedics, Inc., Warsaw, IA); and Zimmer Ortho Guidance Systems (Zimmer, Inc., Warsaw, IN).

Literature Review–Joint Arthroplasty
Several studies evaluating the outcomes of joint replacement using computer-assisted navigation have been published in the medical literature with much emphasis on total knee replacement. Data evaluating computer-assisted navigation for improving accuracy during other orthopedic-related surgical procedures is limited. Few studies evaluate the relevance of computer-assisted navigation on functional outcomes and quality of life, and a number of authors suggest further scientific study is needed to support widespread use in clinical practice (Crockarell, Guyton, 2007; Harkass, Crockarell, 2007).

Regarding joint replacement, the published evidence consists primarily of randomized controlled trials, retrospective and prospective case series, meta-analyses, systematic reviews and review articles. The clinical outcomes of computer-assisted navigation have been compared to conventional surgery, although few trials have evaluated whether or not the accuracy of computer-assisted systems improves long-term health outcomes such as pain, function and need for revision. Additionally, various navigation systems and surgical approaches have been evaluated making comparisons across studies and interpretation of outcomes difficult.

Total Hip Arthroplasty (THA): Prospective randomized and comparative trials demonstrate the use of computer navigation systems for THA is associated with increased operative time (Parrate and Argenson, 2007; Kalteis, et al., 2006) and a learning curve (Ybinger, et al., 2007). However, the published evidence indicates alignment of the hip component is improved with computer navigation systems (Beckman, et al., 2009; Gandhi, et al., 2008; Ecker, et al., 2007; Parrate and Argenson, 2007; Kalteis, et al., 2006; Wixson and MacDonald, 2005; Leenders, et al., 2002). In two of the published trials, the difference in variation of position of the acetabular component was significant and favored navigation systems (Parrate and Argenson, 2007; Kalteis, et al., 2006).

Gandhi and associates (2008) conducted a systematic review and meta-analysis evaluating whether or not navigation increased the precision of acetabular components. The authors reviewed three randomized controlled trials involving 250 patients that met the inclusion criteria (Kalteis, et al., Leenders, et al., Parratte and Argenson). The results of the meta-analysis indicate that computer navigation improved the surgeon's ability to place the acetabular cup within the desired alignment although it was unclear to the authors if improved alignment would translate into improved long-term clinical outcomes.

Beckman et al. (2009) conducted a review of randomized controlled trials evaluating navigated cup implantation during THA. Based on a meta-analysis of five eligible studies reviewed, the authors concluded that altogether the methodological quality was moderate. Navigation reduced variability in cup positioning and was statistically significant compared to conventional freehand positioning and reduced the placing of acetabular components beyond the designated safe zone. However, factors other than cup orientation are involved in the overall success of THA and long term outcomes evaluating durability of the prosthesis and patient satisfaction are still required.

The general consensus among authors is that more accurate alignment leads to better function and durability of the prosthetic device. However, this has not been proven in the published medical literature. Studies have primarily assessed alignment outcomes in the short- to medium-term; many evaluate alignment in the immediate postoperative period and long term outcomes have not been reported. Improving alignment is clinically significant; however CAOS is associated with increased operating time and a learning curve. Well-designed studies demonstrating improved health outcomes, such as improved function, implant longevity, reduced need for revision and improved quality of life (e.g., decreased pain and increased range of motion) are needed to support the advantages of using this technology.

Total Knee Arthroplasty (TKA): Similar to THA, authors contend that computer navigation improves the accuracy of implanting the total knee prosthesis and will improve functional outcomes and lengthen implant survival. Evidence in the form of randomized controlled trials, prospective and retrospective case series and published reviews demonstrates there is improved alignment when compared to conventional approaches (Keene, et al., 2006; Chin, et al., 2005; Bolognesi and Hofmann, 2005; Haaker, et al., 2005; Decking, et al., 2005; Sparmann, et al., 2003), however, some authors have reported no significant differences in prosthesis alignment among study groups (Bauwens, et al., 2007; Kim, et al., 2007). Computer navigated TKA has been associated with longer duration of surgery and tourniquet time (Kim, et al., 2009; Dutton, et al., 2008; Bauwens, et al., 2007; Kim, et al., 2007; Decking, et al., 2005; Bolognesi, Hoffman, 2005).The follow-up duration within most of the early published studies ranged from the immediate post-operative period to approximately 2.5 years post surgery and functional outcomes were either not reported, or were reported but were not statistically different when compared to conventional approaches.

There is a growing body of evidence evaluating the effects of computer-assisted navigation on TKA and more recent studies continue to support improvement in component alignment. Tingart et al. (2008) conducted a prospective case series involving 1000 patients who underwent computer navigated TKA (n=500) or a conventional approach (n=500). In the computer-assisted group 94.8% of patients had a postoperative leg axis within range of ±3° compared to 74.4% in the conventional group. Outliers exceeding ±3° of varus/valgus deviation from the neutral leg axis were seen in 26 cases compared to 128 cases in the conventional group. Restoration of the mechanical axis and component alignment in the computer navigated group was significantly better compared to the conventional group.

Dutton et al. (2008) published the results of a prospective randomized trial (n=108) suggesting that the main advantage of computer navigation is improved postoperative alignment without short-term complications. Clinical parameters, long-leg radiographs and functional assessment scores were evaluated for six months. following surgery. Those patients who underwent conventional TKA had shorter operating times (by 24 minutes) and longer hospital stays (4.5 days compared to 3.3). At one month follow-up significantly more patients in the CAOS group were able to walk independently for more than 30 minutes compared to the conventional group. A total of 92% of the patients in the CAOS group had a coronal tibiofemoral angle within ±3° of the ideal compared to 68% of the patients in the conventional group. The difference was not significant at three and six months. At six months similar improvements were noted in the mean scores of both groups, including the Oxford knee score, Knee Society score, and Short Form-36 scores.

Molfetta and Caldo (2008) reported the results of a retrospective case-control study comparing the computer-assisted TKA (n=30) with conventional TKA (n=30), at an average of five year follow-up. The average surgical time for the navigated group was longer compared to the conventional group; 98 minutes and 82 minutes, respectively. There were no significant differences between groups for knee score assessments and range of motion. A statistically significant difference was noted in the restoration of the mechanical axis in the coronal plane but not the sagittal plane using the navigational system. The authors acknowledged further study is warranted evaluating mechanical failure rates in order to determine whether or not navigation produces longer implant survival. In addition, the authors commented that each navigation system relies on different specifications and as a result, specific studies for each navigation system are needed.

Luring et al. (2009) reported the results of retrospective matched-pair analysis of 50 patients who underwent TKA; 25 patients underwent navigated TKA and 25 underwent conventional TKA. In this study the authors compared WOMAC score, Knee Society score, range of motion, leg alignment, knee stability and isokinetic muscle strength two years after the procedure. Results for WOMAC, Knee Society, and isokinetic muscle force were similar in both groups. The navigated group demonstrated statistically significant better values for post-operative leg alignment in addition to slightly better knee stability and range of motion.

Kim et al. (2009) reported the results of a prospective comparative trial involving 170 patients who underwent primary bilateral TKA. Each patient underwent a computer navigated TKA in one knee and a conventional TKA in the other knee. Pre and postoperative Knee Society Scores improved in groups as well as pre and postoperative range of motion. Operating time and tourniquet times were longer in the computer navigated group. There was no significant difference in the accuracy of component positioning and the number of outliers.

Other authors have also reported improved component positioning and limb alignment (Weng, et al., 2009) using navigation systems when compared to conventional TKA. More recently it has been reported that intraoperative blood loss for patients who underwent navigated TKA was less than that of those who underwent conventional TKA (Conteduca, et al., 2009). Browne et al. (2010) compared the early postoperative outcomes of computer navigated TKA to standard conventional TKA using a large nationwide database and reported that after adjustment for patient characteristics, the authors found no differences in postoperative mortality or complications for the majority of measured outcomes (in-hospital complications, in-hospital mortality, length of hospital stay, rate of non-routine discharge and total charges). Nonetheless, using multivariate regression analysis computer navigation was associated with less postoperative cardiac complications in addition to a shorter length of stay and a trend toward fewer hematomas.

One group of authors has reported that improved alignment correlated with improved knee function scores and quality of life. Choong and colleagues (2009) reported the results of a randomized controlled trial comparing the alignment, function and patient quality-of-life outcomes between patients who underwent conventional and computer-assisted TKA (=115). Median operating time was longer for the computer-assisted group, although there was no difference in blood loss between groups. Median length of hospital stay was 6 days for both groups. There were nine complications in the computer-assisted group and seven in the conventional group. A total of 88% from the navigated group versus 61% of the conventional group achieved a mechanical axis within 3° of neutral. Patients with a mechanical axis within 3° demonstrated superior total International Knee Society scores and Short-Form 36 scores at 6 weeks, 3 months, 6 months, and 12 months following surgery. Another recent study published by Longstaff et al. (2009) has demonstrated that improved component alignment correlates with improved function, quality of life, more rapid rehabilitation and earlier hospital discharge in subjects who underwent conventional total knee replacement followed for one year post surgery (n=159).

Kamat et al. (2009) compared outcomes of computer navigated (n=263) and conventional TKA (n=302) over five consecutive years. Surgical and nonsurgical complications were similar in both groups; there was one revision operation in each group which involved resurfacing of an un-resurfaced patella. There was no significant difference between the average Oxford Knee Scores (OKS) of the two groups at any time from one to five years. At three year follow-up radiograph analysis revealed 15.5% of TKAs in the conventional group and 2.9% of TKAs in the computer-assisted group were aligned beyond 3º of the mechanical axis.

Despite outcomes consistently demonstrating that computer-assisted navigation improves component alignment, data evaluating the advantages of improved alignment on long term implant survival is lacking. Additionally, comparison of outcomes across study groups is confounded by technical differences between navigating systems and different tools for evaluating knee and function scores. The potential benefits and clinical utility of computer-assisted navigation as an adjunct to conventional TKA surgery has yet to be established.

Shoulder Arthroplasty: Similar to hip and knee arthroplasty, success of shoulder arthroplasty also depends on technique. Incorrect component alignment can lead to loosening, instability and sub-optimal function of the joint. Computer navigation has been employed to determine if systems similar to those used in hip and knee surgery are safe and effective for use during shoulder arthroplasty. There are few published clinical studies in the medical literature evaluating computer-aided shoulder navigation and limited published articles. A single published study by Edwards et al. (2008) consisted of a cadaver and an initial cohort of shoulder arthroplasty patients (n=27). Preliminary results have shown the technique is safe and may enhance correction of deformity. Kircher et al., (2009) reported the results of a prospective randomized trial of subjects who underwent shoulder arthroplasty with (n=10) and without intraoperative navigation (n=10). The authors noted improved accuracy of glenoid positioning in the transverse plane using navigation in addition to longer operative times. While preliminary results are encouraging, the evidence is insufficient to support conclusions regarding improved clinical health outcomes and further studies are warranted.

Ankle Arthroplasty: There are a few preliminary trials in the peer-reviewed published scientific literature evaluating the use of computer-assisted navigation for treating osteochondral lesions of the talus. However, studies addressing the use of computer navigation specifically for ankle arthroplasty were not found in the published scientific literature or available textbook sources. Due to the lack of sufficient evidence no conclusions can be made regarding safety and efficacy for this intended use.

Literature Review–Miscellaneous Surgical Procedures

Computer-assisted navigation has been applied to other types of surgical procedures such as reconstruction of anterior cruciate ligaments, osteochondral grafting procedures, spinal surgery and for treatment of various fractures. Although theoretically computer-assisted navigation improves placement and alignment of components, data demonstrating improved patient outcomes as a result of improved placement is lacking.

Spine Procedures: Theoretically, CAS as an adjunct to conventional spinal surgery such as pedicle screw placement may improve the precision of screw placement, decreasing the risk for neural, great vessel, or other soft-tissue injury. CAS has also been employed as an adjunct to facet screw placement and cervical screw placement. Similar to joint arthroplasty procedures there are a number of published studies in the medical literature demonstrating that CAS improves positioning (Lee, et al., 2007; Ito, et al., 2007; Kotani, et al., 2007; Rajasekaran, et al., 2007), however reduced complication rates, increased functional outcomes and improvement in pain scores as a result of improved positioning has yet to be demonstrated. Verma et al. (2010) conducted a systematic review and meta-analysis evaluating the overall benefits of improved placement using computer-assisted navigation during spine procedures. The authors reviewed 23 clinical trials in total: 2 RCTs, 12 case-control studies, and nine case series. A total of 719 patients underwent pedicle screw insertion using navigation and 569 patients underwent conventional screw insertion. Surgical indications included kyphosis, scoliosis, and treatment for metastasis, rheumatoid arthritis and trauma. There were no complications in the navigated group while in the conventional group there were 13 complications. None of the studies reported on the rate of fusion and none provided patient-based health outcome scores such as Oswestry disability index or SF-36 scores. Accuracy data was reported in all studies reviewed and favored the navigation group (93.3%) in comparison to the conventional group (84.7%). There were no statistically significant differences in the available clinical outcomes. The authors concluded the evidence did not favor CAS over conventional methods.

Fracture Treatment: CAS has also been used as an adjunct to fracture treatment for pelvic and femoral fractures. Typically, fluoroscopic guidance is used to provide imaging during these procedures however this type of guidance is limited to viewing a single plane. As a result, repositioning and multiple images are necessary to verify placement. Theoretically CAS promotes improved fixation and reduced exposure to radiation. Data evaluating the use of CAS for treatment of fracture however is limited and consists mainly of feasibility studies, control and comparison groups are lacking. Additional clinical trials are required to support the efficacy of this technology and improvement in health outcomes.

Anterior Cruciate Ligament Reconstruction: CAS is also being investigated for use in ACL reconstruction procedures as a method of restoring improved knee kinematics (Kendoff, et al., 2008). Several of the studies in the published scientific literature focus on the feasibility of CAS for ACL reconstruction with few authors reporting on clinical outcomes. Plaweski et al. (2006) published the results of a randomized controlled trial of 60 subjects who underwent ACL reconstruction using either manual or computer assisted guidance for tunnel placement. At 24 month follow-up, the study results demonstrated that accuracy and consistency of tibial tunnel position are improved with CAS with improvement in graft function. When measuring laxity there was no difference between groups although the variation in laxity was reduced using CAS. Hart et al. (2008) reported the results of a randomized controlled trial evaluating the biomechanical, functional and radiographic results following ACL reconstruction using CAS (n=80). CAS resulted in more exact tunnel placement on the femoral side. Functional scales and stability test results were similar in both CAS and conventional groups. The authors concluded, “The scientific evidence does not yet support definitive relations between long term outcomes and repeatability of positioning or the superiority of one ideal location versus another. “ In contrast to these two studies Endele et al (2009) reported their results of a randomized controlled trial evaluating CAS on tunnel placement during ACL reconstruction (n=40). At two year follow-up the authors reported there was no significant difference between CAS and manually navigated ACL reconstruction with regard to tunnel placement and clinical results.

Technology Assessments
The Blue Cross and Blue Shield Association (BCBS) Technology Evaluation Center (TEC) published a technology assessment to determine whether computer-assisted navigation improves the accuracy of implant alignment for TKA and whether the amount of improvement results in a meaningful improvement in health outcomes, including pain, function or the need for revision surgery. Based on their assessment of the literature reviewed, the evidence was not sufficient to conclude there was more accurate implant alignment. The use of computer-assisted navigation for TKA did not meet TEC criteria (Lefevre, et al., 2008).

ECRI reported their findings on computer-assisted navigation for total hip replacement (ECRI, 2006a) and total knee replacement (ECRI, 2006b) in published emerging technology reports. ECRI stated that for both hip and knee replacement procedures, there is insufficient evidence available to determine whether using computer-assisted navigation systems reduces long-term post-procedure complications (i.e., increased wear, bone fracture, reduced range of motion, and need for revision). ECRI conducted updated literature searches in 2008 for both surgical procedures using computer-assisted navigation and concluded the evidence was insufficient and did not change the conclusions of the prior reports.

The Ontario Health Technology Advisory Committee (OHTAC) conducted a systematic review of computer-assisted hip and knee arthroplasty using navigation and robotic systems (OHTAC, 2004). The committee concluded studies to date on computer-assisted arthroplasty have only assessed short-term outcomes, and long-term effectiveness, such as the need for revision, implant longevity, occurrence of pain and functional performance, has not been demonstrated.

Professional Societies/Organizations
The American Association of Hip and Knee Surgeons (AAHKS) published a position statement on computer-assisted surgical approaches for THA and TKA (AAHKS, 2007). According to the statement, computer-assisted surgery is considered a technology that is currently evolving and is being evaluated world-wide, although it has not been widely adopted. Few complications have been reported, and currently short-term studies demonstrate the technology adds reliability to THA and TKA. Longer studies are needed to clearly establish indications, limitations and complications of the technology. Future studies will also determine if the reported improvements from computer assisted surgery will increase joint implant longevity, and improve overall outcomes for patients. The position has not been updated since 2007.

Summary
There is insufficient evidence to allow strong scientific conclusions regarding the superiority or added value of computer-assisted technologies for musculoskeletal and spine surgery compared to conventional methods. Authors have reported short-term clinical outcomes in some studies; long-term effectiveness has not been firmly established. While there is evidence to support improved alignment, further studies are needed to determine if improved alignment results in improved clinical outcomes such as decreased pain and disability, improved range of motion, joint function, flexibility and less revision surgery.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures; image-less (List separately in addition to code for primary

	procedure)
20986	Computer-assisted surgical navigational procedure for musculoskeletal procedures; with image guidance based on intraoperatively obtained images (eg, fluoroscopy, ultrasound) (List separately in addition to code for primary procedure) (Deleted 01/01/2009)
20987	Computer-assisted surgical navigational procedure for musculoskeletal procedures; with image guidance based on preoperative images (List separately in addition to code for primary procedure) (Deleted 01/01/2009)
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/MRI images (List separately in addition to code for primary procedure)

ICD-9-CM Diagnosis Codes	Description
	All codes

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	6/15/2008	0454	Computer-Assisted Guidance for Orthopedic Surgery