Coverage Guidelines

Computer-Aided Surgery (CAS) for Total Knee Arthroplasty (TKA)

Disclaimer:
Please note that Baptist Health Plan updates Coverage Guidelines throughout the year. A printed version may not be most up to date version available. The health plan reserves the right to review and update this policy as needed. Refer to the website to ascertain that you are utilizing the most current available version. Clinical guideline policies are not intended to serve as treatment guidelines or treatment recommendation. Treating providers must use their own clinical judgment in rendering care to their patient population.

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, http://www.cms.gov. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

DEFINITION

The emergence of computerized intraoperative limb-alignment technologies suggests a breakthrough in modern surgical technique with man and machine operating together. An example of this interdependent treatment is in the use of computerized assistance in orthopedic surgery, where total knee arthroplasty (TKA) has generated great interest in these new technologies of computer-assisted manipulation (e.g., more accurate anatomical alignment of the limb) and precision in orthopedic device implantation. Over the last decade attempts have been made to demonstrate an efficacious and safe advancement of these techniques in lieu of traditional orthopedic practice in this regard.¹

COVERAGE CRITERIA

Baptist Health Plan considers the use of computer-aided surgery (CAS) for TKA with or without radiographic control to be investigational and therefore not medically necessary.
MEDICAL BACKGROUND

The lack of clear evidence of the usefulness of computer-assisted navigation systems in knee arthroplasty has impeded universal acceptance of this technology in the orthopedic community. The American Academy of Orthopedic Surgeons (AAOS) 2015 guidelines state that there is “strong evidence” to support not using intraoperative navigation in TKA because there is no difference in outcomes or complications.\(^2\)

A contemporary systematic review inclusive of 3504 patients found no significant differences in outcomes between surgery with computer-navigated TKA controlling for alignment and component positioning versus conventional TKA (\(p = 0.63\)). However, significantly better outcomes were noted following computer-navigated TKA that also controlled for soft tissue balancing versus conventional TKA (mean difference 4.84, 95% Confidence Interval 1.61, 8.07, \(p = 0.003\)).\(^3\)

A systematic review and meta-analysis evaluated the effects of computer navigation on blood product usage by comparing postoperative blood loss and need for allogenic blood transfusion in patients undergoing computer navigation and conventional primary TKAs. The change in hemoglobin concentration was 0.39 g/dl lower with computer navigation than with conventional TKA (\(P = 0.006\)). Blood loss via drainage was 83.1 ml (\(P = 0.03\)) lower and calculated blood loss was 185.4 ml (\(P = 0.002\)) lower with computer navigation than with conventional TKA.\(^4\)

A systematic review inclusive of 490 patients with computer-assisted minimally invasive TKA and 503 similar patients undergoing conventional TKA without computer-aided intervention found there was no significant difference in the outliers on complications, knee flexion, and postoperative functional scores. Coronal plane tibial component showed statistically significant superiority in component positioning in the computer-assisted group; however, intra-operative time was significantly longer in the computer-assisted group with a mean increase of 32 minutes.\(^5\)

A second systematic review confirmed that use of imageless computer-assistance during TKA improves coronal and sagittal knee prosthetic alignment.\(^6\)

A systematic review on unicompartmental knee arthroplasty (UKA) found computer-assisted implant alignment was optimal in the desired angular range more often, and there were fewer outliers than in non-assisted controls. However, the groups did not differ with respect to clinical knee scores, survival rates, or range of motion. Longer surgery times in the navigation group was also noted.\(^7\)

A systematic review found computer navigation in TKA produced more reliable results, but the technology’s impact on functional outcomes remains unclear. TKA performed with computer navigation was more likely to be within 3° of ideal mechanical alignment (87.1% vs. 73.7%, \(P < .01\)). On the other hand, computer-assisted TKAs had only a marginally significant higher increase in functional score at 3-month follow-up (68.5 vs. 58.1, \(P = .03\)) and at 12-32 month follow-up (53.1 vs. 45.8, \(P < .01\)).\(^8\)

A systematic review and meta-analysis inclusive of 2089 patients (computer-navigated TKA=1111, conventional TKA=978) compared outcomes with regard to desired post-operative mechanical axis and complications. Although patients undergoing computer-navigated TKA had fewer outliers in mechanical axis (13.4%) compared with the conventional technique (27.4%), the results did not achieve statistical significance (I2=0.0%; \(P=1.000\)). A significant increase of
16.9 minutes in mean operative time for computer-navigated TKA was observed (P=.046). Fewer complications were observed in patients undergoing computer-navigated TKA (4%) compared with conventional TKA (6.5%).

The following Hayes ratings have been established for this technology:

- C (Potential but unproven benefit) – For CT-based CAS for TKA for adult patients.
- D2 (Insufficient evidence) – For fluoroscopy-based CAS for TKA. This Rating is based on the limited number of studies evaluating the effectiveness and safety of fluoroscopy-based CAS.
- D2 – For image-based CAS for TKA in children. This rating is based on the lack of studies investigating image-based TKA in children.
- C – For imageless CAS TKA for adult patients.
- D1 (No proven benefit/unsafe) – For imageless CAS for TKA for patients with contraindications for TKA. This Rating is based on concerns about safety in patients with contraindications.
- D2 – For imageless CAS for TKA in children. This Rating is based on the lack of studies investigating TKA in children.
- D2 – For use of Verasense during TKA. This Rating reflects a sparse and very-low-quality body of evidence that does not allow for definitive conclusions to be drawn regarding the efficacy, comparative effectiveness, and safety of this device. Substantial uncertainty remains due to a lack of controlled studies evaluating the effect of the use of Verasense on clinical outcomes and its comparative effectiveness with other conventional manual soft-tissue balancing techniques. The Verasense disposable sensor-embedded tibial trial was designed to obviate the problem of malignment and is intended for use in both primary and revision TKA.

Hayes notes there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of Makoplasty for osteoarthritis of the knee. The Robotic-arm Interactive Orthopedic (RIO) system from Mako Surgical Corporation uses patient CT data to assist the physician with pre-surgical TKA implant placement planning and intraoperative tracking of the patient’s femur and tibia.

UpToDate opines that “the role of techniques such as . . . surgical computer-assisted navigation….” in TKA remains to be defined.

**REGULATORY INFORMATION**

Kentucky – No legislative mandates were found for coverage of computer aided surgery for total knee replacement procedures.

Indiana – No legislative mandates were found for coverage of computer aided surgery for total knee replacement procedures.
Tennessee – No legislative mandates were found for coverage of computer aided surgery for total knee replacement procedures.

The FDA has approved a large number of CAS systems for TKA:

- VectorVision CT-Free Knee (Brainlab AG) (K021306, approved on October 25, 2002) (CDRH, 2002a)
- Navitrack System Optical TKIR CT-Less (Orthosoft Inc.) (K021760, approved on August 27, 2002) (CDRH, 2002b)
- PiGalileo Total Knee Replacement (TKR) System (PLUS ORTHOPEDICS AG) (K061362, approved on October 6, 2006) (CDRH, 2006)
- DePuy CAS Knee Instrumentation (DePuy Orthopaedics, Inc.) (K043223, approved on March 3, 2005) (CDRH, 2005a)
- Surgetics ORTHO KNEELOGICS Navigation System (Praxim) (K031196, approved on June 7, 2005) (CDRH, 2005b)

Some of these systems can be used for image-based or imageless surgery, depending on the software used (e.g., VectorVision).

Verasense is categorized as a class II device under “intraoperative orthopedic joint assessment aid.” Its most recent clearance summary states that the Verasense Knee System is indicated for any medical condition in which primary or revision TKA would be indicated. Verasense was subject to a class II recall on January 29, 2015. The reason for the recall was “Presence of one inoperable (dead) sensor pad.”

Mako Surgical Corporation has received several FDA 510(k) clearances for the Makoplasty components. Eleven recalls were located for Mako Surgical products associated with the Makoplasty procedure. FDA device recalls can be found on the Medical Device Recalls database.

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**COVERAGE DETAIL**

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.

CODES INCLUDE BUT MAY NOT BE LIMITED TO THE FOLLOWING:
## CPT® Codes

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<tr>
<th>CPT® Codes</th>
<th>Description</th>
<th>Coverage Information</th>
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<tr>
<td>20985</td>
<td>Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (list separately in addition to code for primary procedure)</td>
<td>Not medically necessary and/or experimental/investigational for Total Knee Replacement Arthroplasty</td>
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<tr>
<td>0054T</td>
<td>Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (list separately in addition to code for primary procedure)</td>
<td>Not medically necessary and/or experimental/investigational for Total Knee Replacement Arthroplasty</td>
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<tr>
<td>0055T</td>
<td>Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (list separately in addition to code for primary procedure)</td>
<td>Not medically necessary and/or experimental/investigational for Total Knee Replacement Arthroplasty</td>
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## ICD.10-PCS Codes

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<tr>
<td>8E0YXBZ</td>
<td>Computer assisted surgery (CAS) of Lower Extremity</td>
<td>Not medically necessary and/or experimental/investigational for Total Knee Replacement Arthroplasty</td>
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## REFERENCES