Policy Statement

Computer-assisted surgery for orthopedic procedures of the pelvis and appendicular skeleton is considered investigational.

Policy Guidelines

The coding for this navigation includes one category I CPT code and two category III CPT codes:

- **20985**: Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (List separately in addition to code for primary procedure)
- **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)

All of the codes are intended to be used in addition to the code for the primary procedure.

Description

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, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Because CAN is a surgical information system in which the surgeon is only acting on the information that is provided by the navigation system, surgical navigation systems generally are subject only to 510(k) clearances from the U.S. Food and Drug Administration (FDA). As such, the FDA does not require data documenting the intermediate or final health outcomes associated
with CAN. (In contrast, robotic procedures, in which the actual surgery is robotically performed, are subject to the more rigorous requirement of the premarket approval application process.)

A variety of surgical navigation procedures have been cleared for marketing by the FDA through the 510(k) process with broad labeled indications. For example, the OEC FluoroTrak 9800 plus is marketed for locating anatomic structures anywhere on the human body.

Several navigation systems (e.g., PiGalileo™ Computer-Assisted Orthopedic Surgery System, PLUS Orthopedics, OrthoPilot® Navigation System, Braun; Navitrack® Navigation System, ORTHOsoft) have received the FDA clearance specifically for TKA. The FDA-cleared indications for the PiGalileo™ system are representative. This system “is intended to be used in computer-assisted orthopedic surgery to aid the surgeon with bone cuts and implant positioning during joint replacement. It provides information to the surgeon that is used to place surgical instruments during surgery using anatomical landmarks and other data specifically obtained intraoperatively (e.g., ligament tension, limb alignment). Examples of some surgical procedures include but are not limited to:

- Total knee replacement supporting both bone referencing and ligament balancing techniques
- Minimally invasive total knee replacement

FDA product code: HAW.

In 2013, the VERASENSE™ Knee System (OrthoSensor) and the iASSIST™ Knee (Zimmer) were cleared for marketing by the FDA through the 510(k) process. FDA product codes: ONN, OLO.

Several computer-assisted navigation devices cleared by the FDA are listed in the table below.

**Table 1. Computer-assisted Navigation Devices Cleared by the U.S. Food and Drug Administration**

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>VERASENSE for Zimmer Biomet Persona</td>
<td>OrthoSensor Inc.</td>
<td>6/7/2018</td>
<td>K180459</td>
<td>Computer-assisted Navigation for Orthopedic Surgery</td>
</tr>
<tr>
<td>NuVasive Next Generation NVM5 System</td>
<td>NUVASIVE INCORPORATED</td>
<td>3/16/2017</td>
<td>K162313</td>
<td>Computer-assisted Navigation for Orthopedic Surgery</td>
</tr>
<tr>
<td>JointPoint</td>
<td>JOINTPOINT INC.</td>
<td>8/3/2016</td>
<td>K160284</td>
<td>Computer-assisted Navigation for Orthopedic Surgery</td>
</tr>
<tr>
<td>EXACTECH GPS</td>
<td>BLUE ORTHO</td>
<td>7/13/2016</td>
<td>K152764</td>
<td>Computer-assisted Navigation for Orthopedic Surgery</td>
</tr>
<tr>
<td>VERASENSE Knee System</td>
<td>OrthoSensor Inc.</td>
<td>4/15/2016</td>
<td>K150372</td>
<td>Computer-assisted Navigation for Orthopedic Surgery</td>
</tr>
<tr>
<td>CTC TCAT(R)-TPLAN(R) SURGICAL SYSTEM</td>
<td>CUREXO TECHNOLOGY CORPORATION</td>
<td>8/18/2014</td>
<td>K140585</td>
<td>Computer-assisted Navigation for Orthopedic Surgery</td>
</tr>
</tbody>
</table>
Rationale

Background

Implant Alignment for Knee Arthroplasty

For TKA, malalignment is commonly defined as a variation of more than 3° from the targeted position. Proper implant alignment is believed to be an important factor for minimizing long-term wear, the risk of osteolysis, and loosening of the prosthesis.

Computer-Assisted Navigation

The goal of CAN is to increase surgical accuracy and reduce the chance of malposition.

In addition to reducing the risk of substantial malignment, CAN may improve soft tissue balance and patellar tracking. CAN is also being investigated for surgical procedures with limited visibility such as placement of the acetabular cup in total hip arthroplasty, resection of pelvic tumors, and 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 the reconstruction of the anterior cruciate ligament.

CAN devices may be image-based or non-image-based. Image-based devices use preoperative computed tomography 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 surgery, 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 the movement of the thigh through a series of circular arcs, with the computer producing a 3-dimensional 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: data acquisition, registration, and tracking.

Data Acquisition

Data can be acquired in three ways: fluoroscopically, guided by computed tomography scan or magnetic resonance imaging or guided by imageless systems. These data are then used for registration and tracking.

Registration

Registration refers to the ability to relate images (i.e., radiographs, computed tomography scans, magnetic resonance imaging, or patients' 3D anatomy) to the anatomic position in the surgical field. Registration techniques may require the placement of pins or "fiducial markers" in the target bone. 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.
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 then provide real-time information of the position and orientation of tool alignment concerning the bony anatomy of interest.

VERASENSE (OrthoSense) is a single-use device that replaces the standard plastic tibial trial spacer used in TKA. The device contains microprocessor sensors that quantify load and contact position of the femur on the tibia after resections have been made. The wireless sensors send the data to a graphic user interface that depicts the load. The device is intended to provide quantitative data on the alignment of the implant and soft tissue balancing in place of intraoperative “feel.”

iASSIST (Zimmer) is an accelerometer-based alignment system with a user interface built into disposable electronic pods that attach onto the femoral and tibial alignment and resection guides. For the tibia, the alignment guide is fixed between the tibial spines and a claw on the malleoli. The relation between the electronic pod of the digitizer and the bone reference is registered by moving the limb into abduction, adduction, and neutral position. Once the information has been registered, the digitizer is removed, and the registration data are transferred to the electronic pod on the cutting guide. The cutting guide can be adjusted for varus/valgus alignment and tibial slope. A similar process is used for the femur. The pods use the wireless exchange of data and display the alignment information to the surgeon within the surgical field. A computer controller must also be present in the operating room.

Due to the lack of any recent studies on pelvic tumor resection, these sections of the Rationale were removed from this evidence review in 2016.

Literature Review
Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

For many orthopedic surgical procedures, optimal alignment is considered an important aspect of long-term success. For example, misplaced tunnels in the anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) reconstruction or malalignment of arthroplasty components are some of the leading causes of instability and reoperation. In total hip arthroplasty (THA), the orientation of the acetabular component of the THA is considered critical, while for total knee arthroplasty (TKA), alignment of the femoral and tibial components and ligament balancing are
considered important outcomes. Ideally, one would prefer controlled trials comparing the long-term outcomes, including stability and reoperation rates.

**Computer-assisted Navigation for Trauma or Fracture**

**Clinical Context and Therapy Purpose**

The purpose of CAN is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual alignment methods, in patients who are undergoing orthopedic surgery for trauma or fracture.

The question addressed in this evidence review is: does the use of CAN improve the net health outcome when used for orthopedic procedures, including surgery for trauma or fracture, ligament reconstruction, THA, periacetabular osteotomy, and TKA?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population of interest are individuals who are undergoing orthopedic surgery for trauma or fracture.

**Interventions**

The therapy being considered is CAN.

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, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

**Comparators**

Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/manual alignment methods include medical reduction procedures, elastic bandaging, splints, and physical therapy. These are performed by a physical therapist and primary care provider in an outpatient clinical setting.

**Outcomes**

The general outcomes of interest are symptoms, morbid events, and functional outcomes.

**Timing**

The existing literature evaluating CAN as a treatment for patients who are undergoing orthopedic surgery for trauma or fracture has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

**Setting**

Patients who are undergoing orthopedic surgery for trauma or fracture are actively managed by orthopedic surgeons in an inpatient surgical setting and by physical therapists and primary care providers following the procedure in an outpatient clinical setting.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
- Studies with duplicative or overlapping populations were excluded
Computer-assisted surgery has been described as an adjunct to pelvic, acetabular, or femoral fractures. For example, fixation of these fractures typically requires percutaneous placement of screws or guidewires. Conventional fluoroscopic guidance (i.e., C-arm fluoroscopy) provides imaging in only one plane. Therefore, the surgeon must position the implant in one plane and then get additional images in other planes in a trial-and-error fashion to ensure that the device has been properly placed. This process adds significant time in the operating room and radiation exposure. Computer-assisted surgery may permit minimally invasive fixation and provide more versatile screw trajectories with less radiation exposure. Therefore, computer-assisted surgery is considered an alternative to the existing image guidance using C-arm fluoroscopy.

Ideally, investigators would conduct controlled trials comparing operating room time, radiation exposure, and long-term outcomes of those whose surgery was conventionally guided using C-arm vs image-guided using computer-assisted surgery. While several in vitro and review studies had been published, when this evidence review was created in 2004, only a single clinical trial of computer-assisted surgery in trauma or fracture cases was identified. CAN for internal fixation of femoral neck fractures was retrospectively analyzed in 2 cohorts of consecutive patients (20 each, performed from 2001 to 2003, at 2 different campuses of a medical center) who underwent internal fixation with 3 screws for a femoral neck fracture. Three of 5 measurements of parallelism and neck coverage were significantly improved by CAN; they included a larger relative neck area held by the screws (32% vs 23%) and less deviation on the lateral projection for both the shaft (1.7° vs 5.2°) and the fracture (1.7° vs 5.5°) screw angles, all respectively. Slight improvements in anteroposterior screw angles (1.3° vs 2.1° and 1.3° vs 2.4°, respectively) were not statistically significant. There were two reoperations in the CAN group and six in the conventional group. Complications (collapse, subtrochanteric fracture, head penetration, osteonecrosis) were lower in the CAN group (3 vs 11, respectively).

Section Summary: CAN for Trauma or Fracture
There is limited literature on the use of CAN for trauma or fractures. Additional controlled studies that measure health outcomes are needed to evaluate this technology.

CAN for ACL or PCL Reconstruction
Clinical Context and Therapy Purpose
The purpose of CAN is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual alignment methods, in patients who are undergoing ligament reconstruction.

The question addressed in this evidence review is: does the use of CAN improve the net health outcome when used for orthopedic procedures, including surgery for trauma or fracture, ligament reconstruction, THA, periacetabular osteotomy, and TKA?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest are individuals who are undergoing ligament reconstruction.

**Interventions**
The therapy being considered is CAN.

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, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

**Comparators**
Comparators of interest include conventional/manual alignment methods. Treatment by means
of conventional/manual alignment methods include medical reduction procedures, elastic bandaging, braces, and physical therapy. These are performed by a physical therapist and primary care provider in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, morbid events, and functional outcomes.

Timing
The existing literature evaluating CAN as a treatment for patients who are undergoing ligament reconstruction has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, two years of follow-up is considered necessary to demonstrate efficacy.

Setting
Patients who are undergoing ligament reconstruction are actively managed by orthopedic surgeons in an inpatient surgical setting and by physical therapists and primary care providers following the procedure in an outpatient clinical setting.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
- Studies with duplicative or overlapping populations were excluded

Systematic Reviews
A Cochrane review (2014) compared the effects of CAN with conventional operating techniques for ACL or PCL reconstruction. Two RCTs (total n=366 participants) on ACL reconstruction were included in the updated review; no studies involved PCL reconstruction. The quality of evidence ranged from moderate- to very-low. Pooled data showed no statistically or clinically relevant differences in self-reported health outcomes (International Knee Documentation Committee subjective scores and Lysholm Knee Scale scores) at two or more years of follow-up. No significant differences were found for secondary outcomes, including knee stability, range of motion, and tunnel placement. Overall, there was insufficient evidence to advise for or against the use of CAN. Four of the five trials included in the Cochrane review are described next.

Randomized Controlled Trials
Plaweski et al (2006) reported on a trial that randomized 60 patients to manual or computer-assisted guidance for tunnel placement with follow-up at 1, 3, 6, 12, 18, and 24 months. There were no differences between groups in measurements of laxity. However, there was less variability in side-to-side anterior laxity in the navigated group (e.g., 97% were within 2 mm of laxity in the navigated group vs 83% in the conventional group at an applied force of 150 N). There was a significant difference in the sagittal position of the tibial tunnel (distance from the Blumensaat line, 0.4 mm vs -1.2 mm, respectively), suggesting possible impingement in extension for the conventional group. At the final follow-up (24 months), all knees had normal function, with no differences observed between groups.

Hart et al (2008) compared biomechanical radiographic with functional results in 80 patients randomized to ACL reconstruction using CAN (n=40) or to the standard manual targeting technique (n=40). The blinded evaluation found more exact bone tunnel placement with CAN, but no overall difference in biomechanical stability or function between groups.
Other studies have found no significant improvement in the accuracy of tunnel placement when using CAN. Meuffels et al (2012) reported on a double-blind controlled trial that randomized 100 patients to conventional or computer-assisted surgery. Evaluation by 3-dimensional computed tomography (CT) found no significant difference between groups for the accuracy or the precision of the femoral and tibial tunnel placement.

**Table 2. Summary of Characteristics of Key RCTs Comparing CAN with Manual Placement for Anterior or Posterior Cruciate Ligament Reconstruction**

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hart (2008)</td>
<td>Czech Republic</td>
<td>1</td>
<td>NR</td>
<td>Patients (n=80) undergoing ACL reconstruction for chronic rupture of the ACL/ only chronic ACL-insufficiency knees were included in the study (&gt;6 mo after injury). Other inclusion criteria were no other prior or simultaneous intra-articular surgical procedure; no cartilage degeneration of meniscal tear; and a normal contralateral knee. Ages ranged from 16 to 39 years with a mean of 29.4. Mean body weight was 74 kg.</td>
<td>CAN (n=40) Manual placement (n=40)</td>
</tr>
<tr>
<td>Meuffels (2012)</td>
<td>Netherlands</td>
<td>1</td>
<td>Jan 2007-Nov 2009</td>
<td>Patients (n=100) patients who were 18 years of age or older and eligible for primary ACL reconstruction without any additional posterior cruciate ligament or lateral collateral ligament injury were included. Exclusion criteria were insufficient grasp of the Dutch or English language and inability or unwillingness to comply with regular postoperative follow-ups. Participants were randomized according to a computer-generated procedure (block randomization utilizing a variable block size);</td>
<td>CAN (n=49) Conventional (n=51)</td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; CAN: computer-assisted navigation; NR: not reported; ACL: anterior cruciate ligament.
### Table 4. Summary of Design and Conduct Gaps in Key RCTs Comparing CAN with Manual Placement

<table>
<thead>
<tr>
<th>Study</th>
<th>Selection</th>
<th>Blinding</th>
<th>Delivery of Test</th>
<th>Selective Reporting</th>
<th>Completeness of Follow Up</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAN</td>
<td>Eligibility criteria were not clearly identified.</td>
<td>Allocation not concealed adequately. The text mentions that &quot;randomization was performed by selection of sealed envelope. It is not clear WHO selected the enveloped. But as they were not described</td>
<td></td>
<td></td>
<td></td>
<td>Thought power was adequate, sample size was too small for clinically significant results</td>
</tr>
</tbody>
</table>

**Note:** RCT: randomized controlled trial; CAN: computer-assisted navigation; IKDC: International Knee Documentation Committee; SD: standard deviation.
<table>
<thead>
<tr>
<th>Study</th>
<th>Selection</th>
<th>Blinding</th>
<th>Delivery of Test</th>
<th>Selective Reporting</th>
<th>Completeness of Follow Up</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hart (2008)&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Randomization techniques are not described in any manner within the text.</td>
<td>Blinding of data collectors and outcome adjudicators lacking (which is crucial to ensure unbiased ascertainment of outcomes); this study employs single masking for the most part (only blinding the participants); an attempt to employ a &quot;double-blind&quot; strategy by using a single &quot;evaluator&quot; at a follow-up and then saying the evaluator is &quot;blinded&quot; to the treatment does occur. It is not clear how this benefits the protocol or enhances the study.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meuffels (2012)&lt;sup&gt;5&lt;/sup&gt;</td>
<td>Allocation concealment not optimal: manual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>It is unclear if the samples were</td>
</tr>
<tr>
<td>Study</td>
<td>Selection</td>
<td>Blinding</td>
<td>Delivery of Test</td>
<td>Selective Reporting</td>
<td>Completeness of Follow Up</td>
<td>Statistical Methods</td>
</tr>
<tr>
<td>---------------</td>
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</tr>
<tr>
<td>Mauch (2007)</td>
<td>Initial sample selection assumption: It is unclear why the athletes were the only population included in the study. As their physical composition would differ from older or less mobile patients, this would cause participant bias. The sample does not represent the general population.</td>
<td>methods, such as the “drawing lots” used in this study, can (in practice) become nonrandom and are difficult to implement—further, they do not leave an audit trail. Therefore, they are not generally recommended.</td>
<td>matched for confounding factors prior to randomization, allowing for bias in statistical models</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CAN: computer-assisted navigation; RCT: randomized controlled trial.

Table 5. Summary of Relevance Gaps in Key RCTs Comparing CAN with Manual Placement

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaweski (2006)</td>
<td>3. incomplete baseline data limitation: baseline data for ALL relevant factors and influencers is not reported</td>
<td></td>
<td></td>
<td>1. Possible confounders and full background information that could influence the outcomes are not described</td>
<td></td>
</tr>
<tr>
<td>Hart (2008)</td>
<td>3. The study setting and source of study participants is missing (as is the referral pattern)—this could create</td>
<td></td>
<td></td>
<td>1.2. While follow-ups are mentioned, the length, nature, duration, and rationale are not described</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Population</td>
<td>Intervention</td>
<td>Comparator</td>
<td>Outcomes</td>
<td>Follow Up</td>
</tr>
<tr>
<td>------------</td>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-----------</td>
</tr>
<tr>
<td>Meuffels (2012)</td>
<td>referral-filter bias</td>
<td>2. Fidelity of intervention protocol: There is a lack of consistency as to the best method for performing the intervention (positioning of a single-bundle ACL reconstruction) among surgeons in the field.</td>
<td>not explored in the text.</td>
<td>1. All possible confounders have not been explored fully nor reported</td>
<td></td>
</tr>
<tr>
<td>Mauch (2007)</td>
<td>4. The study setting and source of study participants is missing (as is the referral pattern)—this could create referral-filter bias</td>
<td>1. All possible confounders have not been explored, other than sex and age.</td>
<td>2. Outcome bias: Since the CAN surgery uses 3d CT measurements, and the conventional does not, this could produce outcome bias in favor of the CAN</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; CAN: computer-assisted navigation; CT: computed tomography; ACL: anterior cruciate ligament.

**Section Summary: CAN for ACL or PCL Reconstruction**

The evidence on CAN for ACL or PCL reconstruction includes a systematic review of five RCTs. These RCTs, of moderate- to low-quality, did not consistently demonstrate more accurate tunnel placement with CAN. No studies have shown an improvement in functional outcomes or need for revision when CAN is used for ACL or PCL reconstruction.

**CAN for THA and Periacetabular Osteotomy**

**Clinical Context and Therapy Purpose**

The purpose of CAN is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual alignment methods, in patients who are undergoing THA and periacetabular osteotomy.

The question addressed in this evidence review is: does the use of CAN improve the net health outcome when used for orthopedic procedures, including surgery for trauma or fracture, ligament reconstruction, THA, periacetabular osteotomy, and TKA?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population of interest are individuals who are undergoing THA and periacetabular osteotomy.

**Interventions**

The therapy being considered is CAN.

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, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.
Comparators
Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/manual alignment methods include medical reduction procedures, and physical therapy. These are performed by a physical therapist and primary care provider in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, morbid events, and functional outcomes.

Timing
The existing literature evaluating CAN as a treatment for patients who are undergoing THA and periacetabular osteotomy has varying lengths of follow-up, ranging from 6-40 months. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Setting
Patients who are undergoing THA and periacetabular osteotomy are actively managed by orthopedic surgeons in an inpatient surgical setting and by physical therapists and primary care providers following the procedure in an outpatient clinical setting.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
d. Studies with duplicative or overlapping populations were excluded

Parratte and Argenson (2007) randomized patients to CAN (n=30) or freehand cup positioning (n=30) for THA by an experienced surgeon. The mean additional time for the computer-assisted procedure was 12 minutes. There was no difference between the computer-assisted group and the freehand-placement group with regard to the mean abduction or anteversion angles measured by CT. A smaller variation in the positioning of the acetabular component was observed in the CAN group; 20% of cup placements were considered to be outliers in the CAN group compared with 57% in the freehand-placement group. In a randomized trial of 125 patients, Lass et al (2014) compared the acetabular component position for CAN and the conventional freehand technique. CT scans identified higher accuracy for acetabular component anteversion, less deviation from the target position for anteversion, and fewer outliers from the target for inclination and anteversion. Surgical time was 18 minutes longer for CAN. Functional outcomes were not assessed.

A study by Manzotti et al (2011) compared leg length restoration in a matched-pair study. Forty-eight patients undergoing THA with CAN were compared with patients who were matched for age, sex, arthritis level, preoperative diagnosis, and preoperative leg length discrepancy and underwent conventional freehand THA using the same implant in the same period. The mean preoperative leg length discrepancy was 12.17 mm in the CAN group and 11.94 mm in the standard group. Surgical time was increased by 16 minutes in the CAN group (89 minutes vs 73 minutes). There was a significant decrease in both the mean postoperative leg length discrepancy (5.06 mm vs 7.65 mm) and the number of cases with a leg length discrepancy of 10 mm or more (5 patients vs 13 patients), all respectively. Outcomes at 40-month follow-up (range, 7-77 months) did not differ significantly for the Harris Hip Score (88.87 vs 89.73) or the 100-point normalized Western Ontario and McMaster Universities Arthritis Index score (9.33 vs 13.21;
p=0.050), all respectively. Longer follow-up with a larger number of subjects is needed to determine whether CAN influences clinical outcomes.

**Minimally Invasive THA**

It has been proposed that CAN might overcome the difficulties of reduced visibility of the surgical area associated with minimally invasive procedures. A review by Ulrich et al (2007) summarized studies that compared outcomes from minimally invasive THA using CAN with standard THA.¹⁰ Seventeen studies were described in this evidence-based review, including 9 prospective comparisons, 7 retrospective comparisons, and 1 large (n=100) case series. Reviewers concluded that alignment with minimally invasive CAN appears to be at least as good as standard THA, although the more consistent alignment must be balanced against the expense of the computer systems and increased surgical time.

Minimally Invasive THA approach with CAN (n=35) compared with conventional posterolateral THA (n=40) was reported by Reininga et al (2013).¹¹ This randomized comparison found no group differences in the recovery of gait at up to six months postsurgery.

**Periacetabular Osteotomy**

In a trial by Hsieh et al (2006), 36 patients with symptomatic adult dysplastic hip were randomized to CT-based navigation or the conventional technique for periacetabular osteotomy.¹² An average of 0.6 intraoperative radiographs were taken in the navigated group compared with 4.4 in the conventional group, resulting in a total surgical time that was 21 minutes shorter for CAN. There were no differences between groups for correction in femoral head coverage or functional outcomes (pain, walking, range of motion) at 24 months.

**Total Hip Resurfacing**

Stiehler et al (2013) reported on short-term radiographic and functional outcomes from a randomized comparative trial of THR using CAN and conventional THR in 75 patients.¹³ For most of the radiographic measures, there were no significant differences between the CAN and conventional THR groups. There were fewer outliers (≥5°) for the femoral component with CAN (11%) compared with conventional placement (32%). At six-month follow-up, there were no differences between groups in the final Western Ontario and McMaster Universities score or Harris Hip Score. The CAN group did show a greater percentage improvement in the Western Ontario and McMaster Universities scores and Harris Hip Score due to differences between groups at baseline.

**Section Summary: CAN for THA and Periacetabular Osteotomy**

Relatively few RCTs have evaluated CAN for hip procedures. Although there was early interest in this technology, no recent RCTs have been identified. There is inconsistent evidence from these small trials on whether CAN improves alignment with conventional or minimally invasive THA. One RCT found improved alignment when CAN was used for hip resurfacing, but there was little evidence of improved outcomes at short-term follow-up. Overall, improved health outcomes have not been demonstrated with CAN for any hip procedure.

**CAN for TKA**

**Clinical Context and Therapy Purpose**

The purpose of CAN is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual alignment methods, in patients who are undergoing TKA.

The question addressed in this evidence review is: does the use of CAN improve the net health outcome when used for orthopedic procedures, including surgery for trauma or fracture, ligament reconstruction, THA, periacetabular osteotomy, and TKA?

The following PICOTS were used to select literature to inform this review.
Patients
The relevant population of interest are individuals who are undergoing TKA.

Interventions
The therapy being considered is 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, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

Comparators
Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/manual alignment methods include medical reduction procedures, elastic bandaging, splints/braces, and physical therapy. These are performed by a physical therapist and primary care provider in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, morbid events, and functional outcomes.

Timing
The existing literature evaluating CAN as a treatment for patients who are undergoing TKA has varying lengths of follow-up, ranging from one-eight years. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Setting
Patients who are undergoing TKA are actively managed by orthopedic surgeons in an inpatient surgical setting and by physical therapists and primary care providers following the procedure in an outpatient clinical setting.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
d. Studies with duplicative or overlapping populations were excluded

Alignment of a knee prosthesis can be measured along several different axes, including the mechanical axis, and the frontal and sagittal axes of both the femur and tibia.

Systematic Reviews
A Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment (2007) evaluated CAN for TKA. Nine studies from seven RCTs were reviewed. Selection criteria for the RCTs included having at least 25 patients per group and comparing limb alignment and surgical or functional outcomes following TKA with CAN or conventional methods. Also reviewed were cohort and case series that evaluated long-term associations between malalignment of prosthetic components and poor outcomes. In the largest of the cohort studies, which included more than 2000 patients (3000 knees) with an average of 5-year follow-up, 41 revisions for tibial component failure (1.3% of the cohort) were identified. The relative risk for age was estimated at 8.3, with a greater risk observed in younger, more active patients. For malaignment (defined as >3° varus or valgus), the relative risk was estimated to be 17.3.
Pooled data from the prospective RCTs showed:

- A significant decrease in the percentage of limbs considered to be outliers (e.g., >3° of varus or valgus from a neutral mechanical axis) with CAN
- Surgical time increased by 10 to 20 minutes in all but 1 study. CAN-associated reduction in blood loss was less consistent, with only some of the studies showing a decrease in blood loss of 100 to 200 mL.
- RCTs that assessed function (up to two years of follow-up) did not find evidence of improved health outcomes. However, the studies were not adequately powered to detect functional differences, and data on long-term follow-up were not available.

Based on the deficiencies in the available evidence (e.g., potential for bias in observational studies; lack of long-term follow-up in the RCTs), TEC reviewers concluded that it was not possible to determine whether the degree of improvement in alignment reported in the RCTs led to meaningful improvements in clinically relevant outcomes such as pain, function, or revision surgery.

A meta-analysis by Xie et al (2012) included 21 randomized trials (total n=2658 patients) that reported on clinical outcomes with or without the use of CAN. Most trials included in the review had short-term follow-up. As was found in the 2007 Blue Cross Blue Shield Association Technology Evaluation Center TEC Assessment, surgical time was significantly increased with CAN for TKA, but there was no significant difference between approaches in total operative blood loss, the Knee Society Score (KSS), or range of motion. Rebal et al (2014) conducted a meta-analysis of 20 RCTs (total n=1713 knees) that compared imageless navigation technology with conventional manual guides. Nine studies were considered to have a low-risk of bias due to the blinding of patients or surgical personnel. Fifteen studies were considered to have a low-risk of bias due to evaluator blinding. The improvement in KSS was statistically superior in the CAN group at 3 months (4 studies; 68.5 vs 58.1, p=0.03) and 12 to 32 months (5 studies; 53.1 vs 45.8, p<0.01). However, these improvements did not achieve the minimal clinically significant difference, defined as a change of 34.5 points.

More recent studies (2014, 2015) have also found longer surgical times and few differences in clinical outcome measures at 1-year follow-up.

### Table 6. Characteristics of Systematic Reviews and Meta-Analyses Investigating TKA

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xie (2012)</td>
<td>PubMed (1966 to August 2011) and EMBASE (1984 to August 2011)</td>
<td>21</td>
<td>Included 2658 patients. Among these 1376 were randomly allocated to the computer-assisted TKA group and 1282 to the conventional group</td>
<td>2658 (25-120)</td>
<td>RCT</td>
<td>NR</td>
</tr>
<tr>
<td>Rebal (2014)</td>
<td>2004-2009</td>
<td>20</td>
<td>a combined 869 knees in the computer-assisted groups, and 844 knees in the control groups for a total of 1,713 knees analyzed</td>
<td>1713 knees</td>
<td>RCT</td>
<td>3 mos and 12-32 mos</td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; NR: not reported; TKA: total knee arthroplasty.

### Table 7. Results of Systematic Reviews and Meta-Analyses Investigating TKA

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
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<td>NR</td>
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<td>1713 knees</td>
<td>RCT</td>
<td>3 mos and 12-32 mos</td>
</tr>
</tbody>
</table>
Effect of CAN on Mid- to Long-Term Outcomes

Most studies comparing outcomes at mid- to long-term generally have shown a reduction in the number of outliers with CAN, but little to no functional difference between the CAN and conventional TKA groups.

Cip et al (2018) published the results of a prospective randomized trial in which 100 conventional TKAs were compared with 100 computer-assisted TKAs with a mean follow-up of 12 years postoperatively. The trial was aimed at determining the long-term outcomes of CAN for TKA as a tool to expedite long-term survival based on improved postoperative implantation. The follow-up rate was 75%. No difference in long-term TKA survival was found between the conventional group (91.5%) and the CAN group (98.2%) at 12-years (p=.181).

Follow-up from 4 randomized trials was published between 2013 and 2016; they assessed mid-term functional outcomes following CAN for TKA. Blakeney et al (2014) reported on 46-month follow-up for 107 patients from a randomized trial of CAN vs conventional surgery. There was a trend toward higher scores on the Oxford Knee Questionnaire with CAN, with a mean score of 40.6 for the CAN group compared with 37.6 and 36.8 in extramedullary and intramedullary control groups. There were no significant differences in the 12-item Short-Form Health Survey Physical Component or Mental Component Summary scores. The trial was underpowered, and the clinical significance of this trend for the Oxford Knee Questionnaire is unclear.

Lutzner et al (2013) reported on 5-year follow-up for 67 of 80 patients randomized to CAN or conventional TKA. There was a significant decrease in the number of outliers with CAN (3 vs 9, p=0.048) but no significant differences between groups on the KSS or EuroQol questionnaire for quality of life. Cip et al (2014) found a significant decrease in malalignment with CAN, but no significant differences in implant survival or consistent differences clinical outcome measures between the navigated (n=100) and conventional (n=100) TKA groups at minimum 5-year follow-up. Song et al (2016) also reported on a reduction in the number of outliers with CAN (7.3% vs 20%, p=0.006), with no significant differences in clinical outcomes at 8-year follow-up. The trial, which assessed 80 patients (88 knees) was powered to detect a 3-point difference in KSS results.

Comparative Studies

Other comparative study designs have found no significant differences in clinical outcomes following CAN. In a comparative study by Kim et al (2009), which assessed 160 bilateral TKAs performed by experienced surgeons in Asia, differences in alignment measures between the conventionally prepared knee and the knee prepared with CAN assistance were minimal. In 2012, this group reported longer term follow-up (mean, 10.8 years) on 520 patients who underwent CAN for 1 knee and conventional TKA for the other knee (randomized). There were no significant differences between groups for knee function or pain measures. Kaplan-Meier survivorship at 10.8 years was 98.8% in the CAN knee and 99.2% for the conventional knee. Two additional nonrandomized comparative studies (2012, 2013) found an improvement in alignment with CAN, but no difference in clinical or functional outcomes at 5-year follow-up compared with conventional TKA.

Hoffart et al (2012) used an alternate allocation design with 195 patients to compare functional outcomes following CAN-assisted TKA with conventional instrumentation. An independent observer performed the pre- and postoperative assessments. After 5 years, complete clinical scores were only available for 121 (62%) patients. There was no significant difference in the frequency of malalignment between groups. The CAN group had a better mean KSS as well as mean function and knee scores. Mean pain scores did not differ between groups. Study limitations included the high loss to follow-up and lack of subject blinding.
Dyrhovden et al (2016) assessed survivorship and the relative risk of revision at 8-year follow-up for 23684 cases from the Norwegian Arthroplasty Register for patients treated with CAN or conventional surgery. Overall prosthesis survival and risk of revision were similar for both groups, although revisions due to malalignment were reduced with CAN (relative risk, 0.5; 95% confidence interval, 0.3 to 0.9; p=0.02). There were no significant differences between groups for other reasons for revision (e.g., aseptic loosening, instability, periprosthetic fracture, decreased range of motion). At 8 years, the survival rate was 94.8% (95% confidence interval, 93.8% to 95.8%) in the CAN group and 94.9% (95% confidence interval, 94.5% to 95.3%) for conventional surgery.

Section Summary: CAN for TKA
A large number of RCTs have assessed outcomes for TKA using CAN or conventional TKA without CAN. Results are consistent in showing reductions in the proportion of outliers greater than 3° in alignment. Results up to 12 years postoperatively have not shown that these differences in alignment lead to improved patient outcomes.

Summary of Evidence
For individuals who are undergoing orthopedic surgery for trauma or fracture, ligament reconstruction, THA and periacetabular osteotomy, or TKA who receive CAN, the evidence includes RCTs and nonrandomized comparative studies. The relevant outcomes are symptoms, morbid events, and functional outcomes. Overall, the literature supports a decrease in the variability of alignment with CAN, particularly with respect to the number of outliers. Although some observational data have suggested that malalignment may increase the probability of early failure, recent RCTs with short- to mid-term follow-up have not shown improved clinical outcomes with CAN. Given the low short-term revision rates associated with conventional procedures and the inadequate power of the available studies to detect changes in function using CAN, studies are needed that assess health outcomes using CAN in a larger number of subjects with longer follow-up to permit greater certainty on the impact of this technology. The evidence is insufficient to determine the effects of the procedure on health outcomes.

Supplemental Information
Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. In response to requests, input was received from 3 academic medical centers while this policy was under review in 2011. Input was mixed on whether computer-assisted navigation is considered investigational. One reviewer provided additional references on high tibial osteotomy and pelvic tumor resection.

Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
One currently unpublished trial that might influence this review is listed in Table 8.
Table 8. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>NCT01469299a</td>
<td>Prospective Study Measuring Clinical Outcomes of Knee Arthroplasty using the VERASENSE™ Knee System</td>
<td>285</td>
<td>Dec 2016 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

References


**Documentation for Clinical Review**

- No records required
Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

<table>
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<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>0054T</td>
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<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>
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<td>20985</td>
<td>Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (List separately in addition to code for primary procedure)</td>
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<td>HCPCS</td>
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<td>Computer Assisted Procedure of Head and Neck Region</td>
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<td>8E0WXBZ</td>
<td>Computer Assisted Procedure of Trunk Region</td>
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<tr>
<td></td>
<td>8E0XXBZ</td>
<td>Computer Assisted Procedure of Upper Extremity</td>
</tr>
<tr>
<td></td>
<td>8E0YXBZ</td>
<td>Computer Assisted Procedure of Lower Extremity</td>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tr>
<td>06/26/2009</td>
<td>New Policy Adoption</td>
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<tr>
<td>08/12/2009</td>
<td>Coding Update</td>
<td>Administrative Review</td>
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<td>01/06/2012</td>
<td>Policy revision without policy change</td>
<td>Medical Policy Committee</td>
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<tr>
<td>09/30/2014</td>
<td>Policy title change from Computer-Assisted Navigation for Orthopedic Surgery</td>
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<td>Policy revision without policy change</td>
<td>Medical Policy Committee</td>
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<tr>
<td>01/01/2017</td>
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</tr>
<tr>
<td>06/01/2019</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
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</table>

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.
**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.