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

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.

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.

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.
surgery is robotically performed, are subject to the more rigorous requirement of the premarket approval application process.)

A variety of surgical navigation procedures have cleared for marketing by the FDA through the 510(k) process with broad labeled indications. The following is an example:

“The OEC FluoroTrak 9800 Plus provides the physician with fluoroscopic imaging during diagnostic, surgical and interventional procedures. The surgical navigation feature is intended as an aid to the surgeon for locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, long bone or vertebra visible on fluoroscopic images.”

Several navigation systems (e.g., PiGalileo™ Computer-Assisted Orthopedic Surgery System, PLUS Orthopedics; OrthoPilot® Navigation System, Braun; Navitrack® Navigation System, ORTHOsoft) have received FDA clearance specifically for total knee arthroplasty. 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.

### Rationale

#### Background

**Computer-Assisted Navigation**

The goal of computer-assisted navigation (CAN) is to increase surgical accuracy and reduce the chance of malposition. For total knee arthroplasty (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, risk of osteolysis, and loosening of the prosthesis. In addition to reducing the risk of substantial malalignment, 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 reconstruction of the anterior cruciate ligament.

CAN devices may be image-based or non-image-based. Image-based devices use preoperative computed tomography (CT) 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 plateau, and medial and lateral epicondyles. The femoral head center is typically calculated by kinematic methods that involve movement of the thigh through a series of circular arcs, with the computer
producing a 3-dimensional (3D) 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 3 steps: data acquisition, registration, and tracking.

**Data Acquisition**
Data can be acquired in 3 ways: fluoroscopically, guided by CT scan or magnetic resonance imaging (MRI), or guided by imageless systems. These data are then used for registration and tracking.

**Registration**
Registration refers to the ability of relating images (i.e., radiographs, CT scans, MRI, or patients’ 3D anatomy) to the anatomic position in the surgical field. Registration techniques may require the placement of pins or “fiduciary 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 with respect to 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 on 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 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.

**Literature Review**
For many orthopedic surgical procedures, optimal alignment is considered an important aspect of long-term success. For example, misplaced tunnels in 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), 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. Intermediate outcomes include the number of procedures that achieve a predetermined level of acceptable alignment.
Trauma or Fracture

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 1 plane. Therefore, the surgeon must position the implant in 1 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, computed-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 versus image-guided using computer-assisted surgery. While several in vitro and review studies had been published,1-3 when this evidence review was created in 2004, we identified only 1 clinical trial of computer-assisted surgery in trauma or fracture cases.4 Computer-assisted navigation (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.5 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 2 reoperations in the CAN group and 6 in the conventional group. Complications (collapse, subtrochanteric fracture, head penetration, osteonecrosis) were lower in the CAN group (3 vs 11, respectively).

Section Summary: 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.

Anterior or Posterior Cruciate Ligament Reconstruction

A 2014 Cochrane review compared the effects of CAN with conventional operating techniques for ACL or PCL reconstruction.6 Five randomized controlled trials (RCTs; 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 [IKDC] subjective scores and Lysholm Knee Questionnaire scores) at 2 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 5 trials included in the Cochrane review are described next.

In 2006, Plaweski et al 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.7 There were no differences between the 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 and functional results in 80 patients randomized to ACL reconstruction using CAN (n=40) or to the standard manual targeting
technique (n=40). 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. In 2012, Meuffels et al reported on a double-blind controlled trial that randomized 100 patients to conventional or to computer-assisted surgery. Evaluation by 3-dimensional computed tomography (CT) found no significant difference between the 2 groups for either the accuracy or the precision of the femoral and tibial tunnel placement.

In 2007, Mauch et al reported on a trial that randomized 53 patients to manual or computer-assisted ACL by reconstruction by 3 experienced surgeons. Tunnel placement and range variance did not differ between the 2 groups, suggesting that experienced surgeons can achieve the same positioning as CAN.

Section Summary: Anterior or Posterior Cruciate Ligament Reconstruction
The evidence on CAN for ACL or PCL reconstruction includes a systematic review of 5 RCTs. These RCTs, of moderate to low quality, did not consistently demonstrated 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.

Hip Arthroplasty and Periacetabular Osteotomy
Few RCTs have evaluated CAN for hip procedures.

Total Hip Arthroplasty
In a 2007 study, Parratte and Argenson randomized patients to CAN for THA (n=30) or freehand cup positioning (n=30) 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 2014 randomized trial of 125 patients, Lass et al compared the acetabular component position between CAN and the conventional freehand technique. CT scans identified higher accuracy for acetabular component anteversion, deviation from the target position for anteversion, and in outliers from the target for inclination and anteversion. Surgical time was 18 minutes longer for CAN. Functional outcomes were not assessed.

A 2011 study by Manzotti et al 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 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 in 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 (WOMAC) 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 Total Hip Arthroplasty (THA)
It has been proposed that CAN may overcome the difficulties of reduced visibility of the surgical area associated with minimally invasive procedures. A 2007 review by Ulrich et al summarized studies that compared outcomes from minimally invasive THA with CAN and standard THA. 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.

Short-term outcomes of minimally invasive THA approach with CAN (n=35) compared with conventional posterolateral THA (n=40) was reported by Reininga et al in 2013. This randomized comparison found no group differences in the recovery of gait at up to 6 months postsurgery.

*Periacetabular Osteotomy*
A 2006 study randomized 36 patients with symptomatic adult dysplastic hip to CT-based navigation or to the conventional technique for periacetabular osteotomy. 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 for functional outcomes (pain, walking, range of motion) at 24 months.

*Total Hip Resurfacing*
In 2013, Stiehler et al reported short-term radiographic and functional outcomes from a randomized comparative trial of THR with CAN (total hip resurfacing) and conventional THR in 75 patients. For most of the radiographic measures, there was no significant difference 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 6-month follow-up, there were no differences between groups in the final WOMAC score or Harris Hip Score. The CAN group did show a greater percentage improvement in the WOMAC score and Harris Hip Score due to differences between groups at baseline.

**Section Summary: Hip Arthroplasty 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 procedures.

*Total Knee Arthroplasty*
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 2007 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment evaluated CAN for TKA. Nine studies from 7 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 (RR) for age was estimated at 8.3, with a greater risk observed in younger, more active patients. For malalignment (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.
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- 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 2 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.

As a result of deficiencies in the available evidence (e.g., potential for bias in observational studies, lack of long-term follow-up in the RCTs), the 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 2012 meta-analysis included 21 randomized trials (total N=2658 patients) that reported clinical outcomes with or without the use of CAN.19 Most studies included in the review had short-term follow-up. As was found in the 2007 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.20 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 at 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 a longer surgical times and few differences in clinical outcome measures at 1-year follow-up.21,22

**Effect of Computer-Assisted Navigation (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.

Follow-up from 4 randomized trials were published between 2013 and 2016; they assessed mid-term functional outcomes following CAN for TKA. Blakeney et al (2014) reported 46-month follow-up for 107 patients from a randomized trial of CAN versus conventional surgery.23 There was a trend toward higher scores on the Oxford Knee Questionnaire with CAN, with a mean score of 40.5 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 5-year follow-up for 67 of 80 patients randomized to CAN or conventional TKA.24 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.25 Song et al (2016) also reported 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.26 The trial, which assessed 80 patients (88 knees) was powered to detect a 3-point difference in KSS results.

Other comparative study designs have found no significant differences in clinical outcomes following CAN. In a 2009 comparative study of 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 alternate allocation design with 195 patients to compare functional outcomes following CAN-assisted TKA versus 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 the 2 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. Limitations of this study include the high loss to follow-up and lack of subject blinding.

In 2016, Dyrhovden et al compared survivorship and the relative risk of revision at 8-year follow-up for 23,684 cases from the Norwegian Arthroplasty Register. Overall prosthesis survival and risk of revision were similar for the 2 groups, although revisions due to malalignment were reduced with CAN (RR=0.5; 95% CI, 0.3 to 0.9; p=0.02). There were no significant differences between the 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% CI, 93.8% to 95.8%) in the CAN group and 94.9% (95% CI, 94.5% to 95.3%) for conventional surgery.

Section Summary: Total Knee Arthroplasty
A large number of RCTs have compared outcomes between TKA with CAN and conventional TKA without CAN. Results are consistent in showing a reduction in the proportion of outliers greater than 3° in alignment. Results up to 10 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, hip arthroplasty and periacetabular osteotomy, or total knee arthroplasty who receive computer-assisted navigation (CAN), the evidence includes randomized controlled trials (RCTs) and nonrandomized comparative studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Overall, the literature supports a decrease in 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. The input was mixed on whether computer-assisted navigation is
considered investigational. One reviewer provided additional references on high tibial osteotomy and pelvic tumor resection.

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.

**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 (NCD). In the absence of an NCD, 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 1.

**Table 1. Summary of Key Trials**

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<td>Dec 2016</td>
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NCT: national clinical trial.

° 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 benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

#### IE

The following services may be considered investigational.

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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.

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<td>08/12/2009</td>
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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.