BlueCross BlueShield
Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.96 Computer-Assisted Navigation for Orthopedic Procedures

Effective Policy Date: July 1, 2022

Original Policy Date: December 2011

Related Policies:

None

Computer-Assisted Navigation for Orthopedic Procedures

Description

Description

Computer-assisted navigation 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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of computer-assisted navigation improves the net health outcome when used for orthopedic procedures, including ligament reconstruction, surgery for trauma or fracture, hip arthroplasty, periacetabular osteotomy, total knee arthroplasty and spine surgery.

POLICY STATEMENT

Computer-assisted surgical navigation for orthopedic procedures is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Reimbursement for the technical component of computer-assisted navigation may be sought through the use of the CPT codes listed here or through hospital case rates.

FDA REGULATORY STATUS

Because computer-assisted navigation 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 computer-assisted navigation. 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 (eg, PiGalileo™ Computer-Assisted Orthopedic Surgery System, PLUS Orthopedics; OrthoPilot Navigation System, Braun; Navitrack Navigation System, ORTHOsoft) have received the FDA clearance specifically for total knee arthroplasty. 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 (eg, 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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Vital™ Navigation System	Zimmer Biomet Spine, Inc.	12/02/2019	K191722	Computer-assisted Navigation for Orthopedic Surgery
Stryker Navigation System With Spinemap Go Software Application, Fluoroscopy Trackers And Fluoroscopy Adapters. Spinemask Tracker	Stryker Corporation	02/14/2019	K183196	Computer-assisted Navigation for Orthopedic Surgery
NuVasive Pulse™ System	NuVasive Inc.	6/29/2018	K180038	Computer-assisted Navigation for Orthopedic Surgery
VERASENSE for Zimmer Biomet Persona	OrthoSensor Inc.	6/7/2018	K180459	Computer-assisted Navigation for Orthopedic Surgery
StealthStation™ S8 With Spine Software	Medtronic	5/01/2017	K170011	Computer-assisted Navigation for Orthopedic Surgery
NuVasive Next Generation NVM5 System	NUVASIVE Inc.	3/16/2017	K162313	Computer-assisted Navigation for Orthopedic Surgery
Stryker OrthoMap Versatile Hip System	Stryker Corporation	2/23/2017	K162937	Computer-assisted Navigation for Orthopedic Surgery
JointPoint™	JointPoint Inc.	8/3/2016	K160284	Computer-assisted Navigation for Orthopedic Surgery
ExactechGPS	Blue Ortho	7/13/2016	K152764	Computer-assisted Navigation for Orthopedic Surgery
Verasense Knee System	OrthoSensor Inc.	4/15/2016	K150372	Computer-assisted Navigation for Orthopedic Surgery
iASSIST Knee System	Zimmer CAS	9/11/2014	K141601	Computer-assisted Navigation for Orthopedic Surgery
CTC TCAT(R)-TPLAN(R) Surgical System	Curexo Technology Corporation	8/18/2014	K140585	Computer-assisted Navigation for Orthopedic Surgery
Digimatch™ Orthodoc Robodoc Encore Surgical System	Curexo Technology Corporation	5/27/2014	K140038	Computer-assisted Navigation for Orthopedic Surgery

RATIONALE

Summary of Evidence

For individuals who are undergoing orthopedic surgery for trauma or fracture and receive computer-assisted navigation, the evidence includes 2 retrospective clinical trials, reviews, and in vitro studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Functional outcomes were not included in the first clinical trial, although it did note fewer complications with computer-assisted navigation versus conventional methods. The second trial found no differences between groups in rates of fracture reduction or screw positions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing ligament reconstruction and receive computer-assisted navigation, the evidence includes a systematic review of 5 randomized controlled trials (RCTs) of computer-assisted navigation versus conventional surgery for anterior and posterior cruciate ligament. Relevant outcomes are symptoms, morbid events, and functional outcomes. Trial results showed no consistent improvement of tunnel placement with computer-assisted navigation, and no trials looked at functional outcomes or need for revision surgery with computer-assisted navigation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing hip arthroplasty and periacetabular osteotomy and receive computer-assisted navigation, the evidence includes older RCTs, a systematic review, and comparison studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Evidence on the relative benefits of computer-assisted navigation with conventional or minimally invasive THA is inconsistent, and more recent RCTs are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing total knee arthroplasty (TKA) and receive computer-assisted navigation, the evidence includes RCTs, systematic reviews of RCTs, and comparative studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. The main difference found between TKA with computer-assisted navigation and total knee arthroplasty without computer-assisted navigation is increased surgical time with computer-assisted navigation. Few differences in clinical and functional outcomes were seen at up to 12 years post-procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing spine surgery and receive computer-assisted navigation, the evidence includes RCTs, comparative observational studies, and systematic reviews of those observational studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Computer-assisted navigation for pedicle screw insertion was consistently associated with lower rates of screw perforation relative to other screw insertion methods, but evidence on clinical outcomes such as revision rate is inconsistent or lacking, including long-term outcome follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in "Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2012	Replace policy	Policy statement changed to "not medically necessary€.
September 2013	Replace policy	Policy updated with literature search; references 6, 9, 14, 16, 19, 21-23,25-27, and 32 added; policy statement unchanged.
March 2017	Replace policy	Policy updated with literature review through November 7, 2016;references 7,12,21,24, 26 and 32 added; some references removed. Title changed to "Computer-Assisted Navigation for Orthopedic Procedure€. Policy statement unchanged except "not medically necessary€ corrected to "investigational€ due to FDA 510(k) clearance.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; no references added. Policy statement unchanged.
June 2019	Replace policy	Policy updated with literature review through February 4, 2019; references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through February 11, 2020; no references added. Policy statements unchanged
June 2021	Replace policy	Policy updated with literature review through April 3, 2021; references added. Policy statement revised to include spine surgery.
June 2022	Replace policy	Policy updated with literature review through March 3, 2022; references added. Policy statements unchanged.