
Computer Assisted Navigation for Musculoskeletal Procedures

MEDICAL POLICY NUMBER: 375

Effective Date: 4/1/2023	COVERAGE CRITERIA	2
Last Review Date: 1/2023	POLICY CROSS REFERENCES.....	2
Next Annual Review: 1/2024	POLICY GUIDELINES.....	3
	REGULATORY STATUS.....	3
	CLINICAL EVIDENCE AND LITERATURE REVIEW	4
	BILLING GUIDELINES AND CODING	6
	REFERENCES.....	7
	POLICY REVISION HISTORY.....	7

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE CRITERIA

- I. Computer assisted navigation is considered **not medically necessary and not covered** for musculoskeletal procedures.

Note: This policy does **not** apply to the below clinical scenarios. Clinical edits or other plan policies may be in place to appropriately adjudicate these services. See [Policy Cross References](#) below.

- Cranial or spinal stereotactic computer-assisted navigation procedures (CPT 61781-61783) or the use of an operating microscope (CPT 69990).
- Robotic surgical systems (e.g., da Vinci Surgical System; CPT S2900).
- Pre-operative computed tomography (CT)/magnetic resonance (MR) imaging; please refer to Carelon (formerly AIM), the Company imaging utilization review vendor.
- Requests to see an out of network provider for the purpose of receiving a computer assisted procedure.

Link to [Evidence Summary](#)

POLICY CROSS REFERENCES

MEDICAL POLICY CROSS REFERENCES

- [Definition: Medical Necessity, MP38](#)

REIMBURSEMENT POLICY CROSS REFERENCES

- Robotic Surgical Systems, UM1

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

BACKGROUND

Computer-assisted navigation

Computer-assisted navigation (CAN) is the application of computer tracking systems to customize and assist with orthopedic procedures such as total hip arthroplasty and total knee arthroplasty. Navigation involves three basic steps: data acquisition, registration, and tracking. These data can be acquired by fluoroscopy, magnetic resonance imaging or computed tomography, or by imageless systems.

Imageless CAS navigation systems have been developed as a means to provide more accurate guidance during implantation of artificial joints. These systems use infrared cameras or tracking systems to help surgeons decide how much bone to remove and where to attach the components of the artificial knee or hip. In some systems, images obtained from the patient are combined with generic models of leg bones to display three-dimensional images that approximate the anatomy of the patient and the recommended sites and extents of bone modifications. Some of the systems also involve use of pointers and/or light-emitting diodes that are attached to patients and instruments to provide surgical guidance. The surgeries are performed on inpatients by trained orthopedic surgeons using general, spinal, or epidural anesthesia.¹

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Surgical navigation systems require U.S. Food and Drug Administration (FDA) clearance, but generally are subject only to 510(k) clearance since computer assisted surgery is considered analogous to a surgical information system in which the surgeon is only acting on the information that is provided by the navigation system. As such, the FDA does not require data documenting the intermediate or final health outcomes associated with computer assisted surgery.

A variety of computer-assisted navigation devices for orthopedic surgery have been approved by the FDA through the 510(k) process, including but not limited to:

- CTC TCAT -TPLAN Surgical System
- Digimatch Orthodoc Robodoc Encore Surgical System
- ExactechGPS
- iASSIST Knee System
- Intellijoint Navigation System (Hip and Knee)
- JointPoint
- NuVasive Next Generation NVM5 System
- NuVasive Pulse System
- Stryker Navigation System with Spinemap Go Software
- Stryker OrthoMap Versatile Hip System
- Verasense for Zimmer Biomet Persona
- Verasense Knee System
- Vital Navigation System

For additional information on approved FDA surgical navigations systems, search the following site by device name: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of computer assisted navigation as a treatment for musculoskeletal procedures. Below is a summary of the available evidence identified through December 2022.

Hip Arthroplasty

- In 2019, ECRI published a clinical evidence assessment on the Intellijoint Hip (Intellijoint Surgical, Inc.) for intraoperative navigation during hip arthroplasty.² Two retrospective case series were included in the review, totaling 131 patients. Both studies reported dislocations and revision surgery 90 days post-surgery. Only one revision surgery was needed, and no dislocations were reported. These case series had a number of limitations, including retrospective design, no comparison groups, lack of randomization, and small sample sizes. Studies were manufacturer-funded.

ECRI found the evidence was inconclusive for Intellijoint Hip for intraoperative navigation during hip arthroplasty. They concluded: “No comparative data are available to determine how well the Intellijoint Hip system works to reduce complications and risk of revision surgery compared to conventional freehand techniques that do not use navigation or how it compares with other navigation systems. Only 2 small single-arm studies at high risk of bias are available. High-quality randomized controlled trials with at least 2-year follow-up are needed, but none are ongoing.”²

- In 2012, Reininga and colleagues published a randomized controlled trial comparing gait in patients following a computer-navigated minimally invasive anterior approach with conventional posterolateral approach for total hip arthroplasty (THA).³ There were 35 patients

in the CAN group and 40 patients in the conventional THA group. The study found no differences in recovery or spatiotemporal parameters or in angular movements of the pelvis and thorax between the 2 groups. Both groups should improve in gait post surgery. Study limitations include small sample size, lack of blinding in patient groups and no mention of blinding among outcome assessors. The authors concluded that “no evidence was found for a faster recovery of gait following computer-navigated minimally invasive anterior approach for THA.”³

Knee Arthroplasty

- In 2019 (updated 2022), Hayes published a health technology assessment comparing the effectiveness of image-based computer-aided navigation (CAN) versus conventional surgeon-directed navigation for total knee arthroplasty (TKA).⁴ The review included:
 - One randomized controlled trial (RCT) comparing fluoroscopic-based CAN (FI-CAN) with conventional (CONV) TKA
 - Two RCTs and 3 nonrandomized prospective studies comparing computed tomography (CT)-based CAN (CT-CAN) with CONV TKA
 - Two RCTs and 2 nonrandomized prospective studies comparing CT-CAN and imageless CAN

No substantive differences were found between FI-CAN and CONV CAN in postoperative alignment, lateral femur angle, lateral tibia angle, patella shift, patella tilt, or mean Knee Score. Among the 5 studies investigating CT-CAN, each trial reported on different measures of alignment. “While some differences suggesting benefit with CT-CAN over CONV were observed (in 3 of 5 studies), benefits were generally small and of unclear clinical importance; furthermore, not all studies found a benefit. A single study reported on function and reported no significant differences between groups.” When comparing CT-CAN and imageless CAN, Hayes reviewers also found no significant differences in alignment or function.

Hayes gave image-based CAN a D1 rating for use in routine TKA and a D2 rating for FI-CAN. The reviewer concluded: “CT image-based CAN for use in TKA may confer some alignment advantages with unclear clinical benefit over CONV navigation; however, evidence indicates no advantage with CT-based CAN over imageless CAN on alignment and function outcome measures. FI-CAN is addressed by an inadequate quantity of evidence to inform conclusions. Evidence on complications is insufficiently reported to enable critical interpretation of its quality; a minority of included studies reported safety outcomes and it is unclear from published accounts whether no events occurred or if they were not reported.”⁴

- ECRI published a number of clinical evidence assessments on CAN systems for guiding knee arthroplasty:
 - VeraSense Knee System (OrthoSensor, Inc.) for TKA- Evidence was found to be inconclusive based on very low quality comparative data from 4 nonrandomized studies.⁵
 - Lantern Surgical Assistant (OrthAlign, Inc.)- Evidence was found to be inconclusive as there were no studies available to review.⁶
 - Mako Robotic Arm-assisted Surgery System (Stryker Corp.)- Evidence was found to be inconclusive based on 2 systematic reviews, 3 nonrandomized comparison trials, and 2 cost-effectiveness studies comparing Mako to conventional PKA.⁷

CLINICAL PRACTICE GUIDELINES

American Academy of Orthopaedic Surgeons (AAOS)

In 2021, The AAOS published clinical practice guidelines for surgical management of osteoarthritis of the knee. The guidelines state that there is strong evidence that there is “no difference in outcomes, function, or pain between navigation and conventional techniques” for knee arthroplasty. They recommend against CAN.⁸

EVIDENCE SUMMARY

There is enough evidence to show that the addition of computer-assisted navigation (CAN) for musculoskeletal procedures does not improve patient centered outcomes. Moderate quality randomized and nonrandomized trials have found no difference between CAN and standard total knee and hip arthroplasty in terms of patient improvement and adverse events, with some studies finding disadvantages to CAN. Furthermore, the clinical practice guidelines recommend against CAN for treating osteoarthritis of the knee and no guidelines were found in support of it for any musculoskeletal indication. Therefore, CAN for musculoskeletal procedures is considered not medically necessary.

BILLING GUIDELINES AND CODING

General Coding

Specific CPT and HCPCS codes are available to represent CAN services. Code selection will depend on whether or not image guidance is used, and if it is used, which type of imaging is used.

	CAN With Imaging	CAN Without Imaging
<i>Fluoroscopic Images</i>	0054T	N/A
<i>CT/MRI Images</i>	0055T	N/A
<i>No Imaging</i>	N/A	20985

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

*Coding Notes:

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

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8. Surgeons AAoO. Surgical management of osteoarthritis of the knee: Evidence-based clinical practice guideline. Published December 2, 2022. <https://www.aaos.org/globalassets/quality-and-practice-resources/surgical-management-knee/smoak2cpg.pdf>. Accessed 12/13/2022.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
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