NO. 91641

COMPUTER ASSISTED SURGICAL NAVIGATION

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Policy scope: This policy outlines the clinical situations in which computer assisted surgical navigation is considered medically necessary, including pulmonary and orthopedic/musculoskeletal procedures.

Related policies:

- None

I. MEDICAL NECESSITY CRITERIA

Inclusions:

A. Pulmonary Procedures
   1. Computer assisted navigation bronchoscopy procedures (robotic and electromagnetic navigational bronchoscopy) are considered medically necessary when performed in accordance with National Comprehensive Cancer Network (NCCN) Non-Small Cell Lung Cancer guidelines.
   2. All other computer assisted navigation bronchoscopy procedures are considered experimental and investigational

B. Orthopedic/Musculoskeletal Procedures

1. Surgical navigation for use in orthopedic indications (spinal, cranial, and other musculoskeletal procedures) may be considered medically necessary when applicable TurningPoint criteria are met.

Exclusions:

C. Computer assisted surgical navigation for all other indications, including but not limited to ear nose and throat (ENT), maxillofacial, and neurosurgery procedures is considered not medically necessary.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

BACKGROUND

Computer-assisted surgery (also called image-guided surgery) is a broad term used to indicate an operation in which imaging scans and computer technology are used to make a three-dimensional (3-D) model of an organ. In the case of neurosurgery, the 3-D model is of the brain. The neurosurgeons use the model as a guide to safely and precisely navigate to and treat a tumor, vascular malformation, or other lesion in the brain.

For brain tumors, computer-assisted surgery has allowed some tumors that were historically inoperable because of their location to become operable, meaning more

patients are able to be successfully treated with surgery. Also, since they can visualize the tumor in 3-D with this technology, our neurosurgeons can resect tumors more completely while minimizing risk to healthy surrounding tissue, nerves, and blood vessels.

Stereotactic neurosurgery is a form of computer-assisted surgery. Specifically, stereotactic neurosurgery is a technique that uses computer technology, brain imaging, and a coordinate system to produce a 3-D model of the brain in order to locate a lesion.

The coordinate system can be either a rigid mechanical frame surrounding a patient's head, referred to as frame-based stereotactic neurosurgery, or created by using reference points on the patient's skull, referred to as frameless stereotactic neurosurgery. Which technique is used depends on the condition treated.

Computer-assisted navigation (CAN) in musculoskeletal 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 (knee and hip), and verification of intended implant placement. The goal of CAN in musculoskeletal procedures is to increase surgical accuracy and reduce the chance of malposition.

CAN may be image based or non-image based. Image based devices use preoperative **computed tomography (CT) magnetic resonance imaging (MRI)** scans, ultrasounds, or operative fluoroscopy to direct implant positioning. Newer non-image based devices are characterized by the fact that it does not require preoperative and postoperative images for planning and guiding surgery. Instead for these procedures, joint kinetic information and bone morphology information are used for planning and to devise guiding maps. For orthopedics, these systems were originally developed for **total knee arthroplasty (TKA)** and **total hip arthroplasty (THA)** applications.

CAN bronchoscopy procedures include electromagnetic and robotic-assisted navigation. Electromagnetic navigation bronchoscopy (ENB) combines electromagnetic (EM) technology with bronchoscopy to navigate, access, and sample lesions in hard to reach areas of the lungs. The procedure works by generating an EM field around the patient's chest and a specialized EM sensor assists with tracking the scope's position within the field. Unlike traditional bronchoscopy, which provides real-time visual feedback only, ENB uses a computed tomography (CT)-generated digital representation of the patient's bronchial tree in combination with real-time visualization to guide the bronchoscope to the specific area of interest (Hayes, 2023). Robotic assisted bronchoscopy (RAB) includes both EM RAB (such as the Monarch [Johnson & Johnson] platform) and shape-sensing robotic assisted bronchoscopy [ssRAB] such as the Ion Intuitive platform). ssRAB technology is applied in the form of a fiber that is embedded along the robotic catheter, providing real-time shape and location information that is corroborated with the CT scan-derived airway map throughout navigation and specimen acquisition. EMN RAB technology uses an external electromagnetic field generator that localizes and tracks sensors embedded in the robotic catheter and corroborates those signals with the CT scan-derived airway map (Low et al, 2023).

A meta-analysis published by the American College of Chest Physicians in 2022 evaluating the diagnostic yield and complications of robotic-assisted navigation bronchoscopy demonstrated promising results. A total of 31 articles were selected for

full-text review. 12 articles, comprising 1065 patients, were included in the final analysis. Most studies (n=10) were performed in the United States. 7 out of 12 studies (58.3%) included mostly female patients. Mean ages ranged from 63.2- 68.4 years, and median ages ranged from 67 - 71 years. Average size of the nodules ranged between 12.2mm - 25.0mm, and median size ranged between 14.0mm - 26.0mm. Of the studies reporting a smoking history (n=4), the majority of patients (75.4% - 92.0%) had a current or prior smoking history. Seven studies used the Ion Intuitive platform, while 5 studies used the Auris Monarch platform. The pooled diagnostic yield amongst studies that reported them (n=10) was 85.2% (95% CI 78.4 - 91.0%). Pneumothorax rates were reported in all studies and the pooled prevalence was 1.18% (95% CI 0.32- 2.38%). The pooled prevalence of bleeding rates was 0.04% (95%CI 0.00 - 0.04%). The conclusion of this study was that diagnostic yield for patients with pulmonary nodules undergoing robotic assisted navigation bronchoscopy was high, with a pooled diagnostic yield of 85.2%. This yield is higher than reported with conventional bronchoscopy with radial endobronchial ultrasound or bronchoscopy using electromagnetic navigation (Pyarali et al, 2022).

In a prospective, multicenter, randomized clinical trial by Zheng and colleagues (2022), the diagnostic value and safety of endobronchial ultrasound combined with a guide sheath (EBUS-GS) alone was compared with EBUS-GS with an electromagnetic navigational bronchoscopy (ENB) system for diagnosing peripheral pulmonary nodules (PPNs). Patients with PPNs suspected to be malignant were enrolled and randomly assigned to the ENB-EBUS-GS group or the EBUS-GS group. The primary endpoint was the diagnostic yield in each group. The secondary endpoint was the procedural time and other factors affecting diagnostic yield. The safety endpoint was procedural complications. Four hundred participants were enrolled from July 2018 to October 2019, and 385 patients were analyzed, 193 in the ENB-EBUS-GS group and 192 in the EBUS-GS group. The mean nodule size was 21.7 ± 5.3 mm. The diagnostic yields were 82.9% (95% confidence interval [CI], 77.6–88.2%) in the ENB-EBUS-GS group and 73.4% (95% CI, 67.2–79.7%) in the EBUS-GS group. The difference between the two groups was 9.5% (95% CI, 2.6–16.3%), with an adjusted difference of 9.0% (95% CI, 2.3–15.8%) after adjusting for the stratification factors and center. The time to find lesions in the ENB-EBUS-GS group was shorter than in the EBUS-GS group (213.2 ± 145.6 vs. 264.8 ± 189.5 s; P = 0.003). Intraoperative hemorrhage occurred 3.6% of subjects in the ENB-EBUS-GS group and 3.1% in the EBUS-GS group, without significant differences between the two groups. The authors concluded that the novel ENB system combined with EBUS-GS demonstrated improved ability to locate PPNs, achieving a high diagnostic yield for PPNs compared with EBUS-GS alone in a safe and efficient procedure.

CAN is increasingly being used in maxillofacial procedures. A systematic review by Thuman and colleagues (2025) included 42 studies on the use of CAN technology within craniomaxillofacial fracture procedures. The authors found that surgical accuracy ranged from 0.7 to 4 mm and postoperative discrepancy ranged from 0.05 to 8 mm. Benefits included improved intraoperative surgical accuracy (95.2%), improved postoperative surgical discrepancy (52.4%), and decreased total surgical time (35.7%). Limitations reported with iCAN device use included operative technical difficulties (23.8%) and persistent systematic errors during device registration (21.4%). None of the studies discussed cost analysis or risks compared to conventional fixation methods. These preliminary findings suggest favorable surgical outcomes associated with the use of CAN in this application.

Another area of application where surgical navigation has been utilized is ear, nose, and throat (ENT) procedures. A 2019 retrospective study reviewed the records of 96 patients with chronic rhinosinusitis (CRS). 48 patients undergoing endoscopic sinus surgery with surgical navigation (A group) and other 48 without navigation (B group). Data about percentage of complications, olfactory function (Visual Analogue Scale), Sino-nasal Outcomes Test (SNOT-22), Rhinosinusitis Quality of Life (RhinoQoL), recurrence (CT Lund-Mackay score), total nasal resistance (rhinomanometry) and duration of the intervention were collected and analyzed. Results showed a decrease of recurrence rate ($p=0.009$), a reduction of total nasal resistance ($p=0.007$), of frontal recess stenosis ($p=0.04$) and of nasal symptomatology ($p=0.008$). QoL had a better improvement in group A. Rate of other complications and olfactory function did not show statistically significant differences between the two groups. The average calibration time was approximately 11min in the A group. Total time of surgical procedure was not significantly different between the two groups ($p>0.05$). (Galletti et al., 2019)

Evidence on the use of computer assisted surgical navigation in skull base procedures is predominantly observational, with outcomes mainly assessing accuracy and feasibility. Data on clinical outcomes with computer assisted vs traditional techniques used in procedures in skull base proximity is lacking.

III. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
National Comprehensive Cancer Network (NCCN)	Non-Small Cell Lung Cancer
American College of Chest Physicians	Establishing the diagnosis of lung cancer: Diagnosis and management of lung cancer, 3rd ed

IV. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
MONARCH™ Platform (MON-000008)	K243219	1/23/2025
PIGALILEO 4TH GENERATION SYSTEM	K080875	7/18/2008
StealthStation S7 / I7 / Fusion / AXIEM Navigation Systems	K133444	7/25/2014
StealthStation Cranial Software System	K153660	9/14/2016
Fiagon Navigation System	K162176	12/1/2016

Stryker Navigation System – ENT Module	K002732	10/2/2000

V. CODING

CPT/HCPCS Codes

31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])
C7567	Bronchoscopy, rigid or flexible, including fluoroscopic guidance when performed, with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i), with computer-assisted image-guided navigation
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (List separately in addition to code for primary procedure)
61781	Stereotactic navigation, cranial intradural
61782	Stereotactic navigation, cranial extradural
61783	Stereotactic computer-assisted (navigational) procedure; spinal (List separately in addition to code for primary procedure)0054T Computer-Assisted Musculoskeletal Surgical Naviational Orthopedic Procedure Guidance Based On Fluroscopic Images
0055T	Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure Guidance Based On CT/MRI Images

VI. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

To access TurningPoint guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will

supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

VIII. REFERENCES

Pulmonary

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SUMMARY OF CHANGES

Additions:

- Added exclusion for ENT, cranial/maxillofacial, and neurosurgery procedures

Clarifications:

- Updated background and references

Past committee review dates: 05/2024, 05/2025, 05/2026