Priority Health

COMPUTER ASSISTED SURGICAL NAVIGATION No. 91641-R1

COMPUTER ASSISTED SURGICAL NAVIGATION

Effective Date: September 1, 2024 | **Review Dates: 5/24**
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Summary of Changes

Additions:

- Added I. B. Orthopedic/Musculoskeletal procedures: Surgical navigation for use in orthopedic indications (spinal, cranial, and other musculoskeletal procedures) may be considered medically necessary when applicable TurningPoint criteria are met.

I. POLICY/CRITERIA

A. Pulmonary procedures:

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. All other computer assisted navigation bronchoscopy procedures are considered experimental and investigational.

B. Orthopedic/Musculoskeletal procedures:

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

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, 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, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to 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 located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, 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.***

IV. 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 realtime 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.

Guidelines

National Comprehensive Cancer Network (NCCN)

Guidelines for Non-Small Cell Lung Cancer V.3.2024 state that *"Patients with pulmonary nodules may benefit from* ***navigational bronchoscopy (including robotic),*** *radial EBUS, or transthoracic needle aspiration (TTNA)",* and that

"Patients with suspected nodal disease should be biopsied by EBUS, EUS, ***navigational bronchoscopy****, or mediastinoscopy."*

American College of Chest Physicians
Diagnosis and Management of Lung Cancer, 3rd ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (2013): "*In patients with peripheral lung lesions difficult to reach with conventional bronchoscopy,* ***electromagnetic navigation guidance*** *is recommended if the equipment and the expertise are available (Grade 1C)"*

V. CODING INFORMATION

Pulmonary:

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])

Orthopedic/Musculoskeletal:

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

Not Payable:
C1739 Tissue marker, imaging and nonimaging device (implantable)

VI. REFERENCES

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