# Molina Clinical Policy
# Image-Guided Bronchoscopy Evaluation of Pulmonary Lesions
# Policy No. 206

**Last Approval: 06/10/2026**
**Next Review Due By: June 2027**

## DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

## OVERVIEW

Lung cancer is the leading cause of cancer-related deaths in the United States, and pathological confirmation continues to be the benchmark for diagnosis. Biopsy via bronchoscopy is a minimally invasive alternative to transthoracic needle biopsy and is associated with a generally lower risk profile by avoiding puncture of the chest wall and reducing pneumothorax risk. Image-guided bronchoscopy encompasses multiple advanced techniques, including virtual navigation bronchoscopy (VNB), electromagnetic navigation bronchoscopy (ENB), and robotic-assisted bronchoscopy (RAB). The primary goal of image-guided bronchoscopy is to facilitate biopsy of peripheral pulmonary lesions (PPLs) that are difficult or not feasible to reach using conventional flexible bronchoscopy alone (Hayes 2018; Ishida et al. 2011; Shepherd 2025).

**Virtual bronchoscopy (VB)** is a non-invasive imaging modality that generates 3D reconstructions of the tracheobronchial tree from thin-slice computed tomography (CT) scans. VB may provide visualizations of distal airways beyond obstructions and allow assessment of nearby structures such as blood vessels or lymph nodes. However, VB does not allow tissue sampling and does not provide real-time procedural guidance. Therefore, VB is typically used for procedural planning or in conjunction with other navigational techniques rather than as a standalone diagnostic modality (Islam 2025; Shepherd 2025).

**Virtual navigation bronchoscopy (VNB)** is a CT-based planning and navigation technique that uses images to generate a 3D virtual pathway to target peripheral pulmonary lesions. During the procedure, an ultrathin bronchoscope is inserted and advanced through the airways following virtual guidance by matching the airway from the 3D imaging with the real-time images obtained through the bronchoscope (Shepherd 2025).

**Electromagnetic navigation bronchoscopy (ENB)** combines CT-derived 3D airway imaging with electromagnetic sensor-based real-tie tracking to guide bronchoscopic instruments to peripheral pulmonary lesions. A sensor probe is advanced through the working channel of the bronchoscope, allowing navigation beyond the third-generation bronchi. ENB systems do not provide direct visualization of the lesion, and lesion confirmation is frequently supplemented with radial probe endobronchial ultrasound (rEBUS), fluoroscopy, digital tomosynthesis, or cone-beam CT. ENB allows pre-procedural pathway planning and intra-procedural adjustments and may be used for diagnostic biopsy or fiducial marker placement (Islam 2025; Shepherd 2025).

**Robotic-assisted bronchoscopy (RAB)** is an advanced navigational bronchoscopy technique utilizing a robotic platform to control a steerable catheter through the bronchial tree. The catheter diameter is smaller than conventional bronchoscopes, allowing access to more distal airways. Some systems incorporate shape-sensing technology, while others utilize electromagnetic tracking. Key technical features include the ability to maintain catheter stability once the target lesion is reached potentially improving tool-in-lesion accuracy. Limitations include lack of tactile feedback, high capital cost, and dependence on adjunctive confirmation technologies such as rEBUS, fluoroscopy, or cone-beat CT (Islam 2025; Shepherd 2025).

### Regulatory Status

The FDA regulates image-guided bronchoscopy systems as Class II devices through the 510(k) premarket notification

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process. In 2019, the FDA cleared the ILLUMISITE Platform (manufactured by Covidien LLC), an ENB system that replaces its predicate device, the superDimension Navigation System, originally cleared in 2004. The device is indicated for displaying images of the tracheobronchial tree to aid physicians in guiding endoscopic tools in the pulmonary track and to enable marker placement within soft lung tissue. It does not make a diagnosis, is not an endoscopic tool, and is not for pediatric use. The ig4 Image Guided System, an ENB system originally FDA cleared in 2009, which had several subsequent models, was recalled in 2023 by its manufacturer, Olympus Corporation of the Americas. Other notable FDA clearances include the LungPoint System in 2009, the bf-NAVI System in 2010, and the LungVision System in 2017, all of which are VBN systems. Additionally, the Monarch Endoscopy Platform and the Ion Endoluminal System are RAB devices that were FDA cleared in 2018 and 2019 respectively. More information about FDA cleared ENB, VNB, and RAB devices can be found in the FDA 510(k) premarket notification database under product codes JAK, LLZ, and EOQ.

## COVERAGE POLICY

Electromagnetic navigational bronchoscopy (ENB)* may be **considered medically necessary** for Members who require a pathological diagnosis of pulmonary lesions when ONE of the following are met:

1. Pulmonary lesions are inaccessible by standard bronchoscopy approaches
2. Pulmonary lesions are inaccessible by a transthoracic biopsy approach

*Note: Endobronchial Ultrasound (EBUS) may be performed in conjunction with ENB to diagnose and stage lung cancer

Virtual navigation bronchoscopy (VNB) and robotic-assisted bronchoscopy (RAB) for the evaluation of pulmonary lesions are considered **investigational, experimental, and unproven** due to insufficient evidence published in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

**DOCUMENTATION REQUIREMENTS:** Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

## SUMMARY OF MEDICAL EVIDENCE

### Virtual Navigation Bronchoscopy (VNB)

***Randomized Controlled Trials***

Asano et al. (2013) conducted a prospective, multicenter, randomized controlled trial (RCT) to evaluate whether the addition of virtual bronchoscopic navigation (VBN) to ultrathin bronchoscopy improves diagnostic yield for peripheral pulmonary lesions. The study enrolled 350 adult patients with suspected malignant peripheral pulmonary lesions measuring ≤ 30 mm in diameter that had not yet been pathologically confirmed; 334 patients were included in the final analysis (167 in the VBN-assisted group and 167 in the non-VBN-assisted group). All procedures were performed using a 2.8 mm ultrathin bronchoscope. In the VBN group, bronchoscopic navigation was guided by virtual airway images generated from preprocedural CT scans, while the control group relied only on axial CT images for guidance. The primary outcome, overall diagnostic yield, did not differ significantly between groups (67.1% in the VBN group vs. 59.9% in the non-assisted group; p = 0.173). However, subgroup analyses demonstrated significantly higher diagnostic yields with VBN for specific lesion subsets, including right upper lobe (81.3% vs. 53.2%; p = 0.004), lesions located in the peripheral third of the lung (64.7% vs. 52.1%; p = 0.047), and lesions not visible on posterior-anterior chest radiographs (63.2% vs. 40.5%; p = 0.043). Similar subgroup improvements were observed for lesions ≤ 20 mm in diameter. Secondary outcomes showed procedural advantages in the VBN group, including higher rates of fluoroscopic confirmation of tool-in-lesion positioning (92.8% vs. 83.8%; p = 0.011), shorter time to initial sampling (median 6.4 vs. 6.8 minutes; p = 0.021), and reduced fluoroscopy time prior to sampling (1.2 vs. 2.2 minutes; p < 0.001). Despite these technical improvements, diagnostic yield by individual sampling modality did not differ significantly between groups. Adverse events were rare and comparable across both groups. The authors

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acknowledged several limitations, including reliance on two-dimensional fluoroscopy, which may inaccurately reflect instrument position, and heterogeneity in bronchoscopic systems and specimen processing that could affect generalizability. Overall, the study concluded that VBN-assisted ultrathin bronchoscopy does not significantly improve overall diagnostic yield for peripheral pulmonary lesions but may enhance diagnostic performance in select lesion subgroups, particularly right upper lobe, radiographically occult, and peripherally located lesions.

***Systematic Reviews and Meta-Analyses***

Giri et al. (2021) conducted a systematic review and meta-analysis of six randomized controlled trials (RCTs) to compare the diagnostic yield and safety of virtual bronchoscopic navigation-assisted (VBNA) bronchoscopy with non-virtual bronchoscopic navigation-assisted (NVBNA) bronchoscopy for the evaluation of peripheral pulmonary lesions (PPLs). The analysis included a total of 1,626 patients, with 813 in each group. The primary outcomes were overall diagnostic yield and total examination time, while secondary outcomes included complication rates and diagnostic yield stratified by lesion characteristics. Pooled analysis demonstrated no statistically significant difference in overall diagnostic yield between the VBNA and NVBNA groups (74.17% vs. 69.51%, respectively; p = 0.13). However, the VBNA bronchoscopy was associated with significantly shorter total examination time, with a mean reduction of approximately four minutes compared with NVBNA (p = 0.003). Subgroup analysis found VBNA achieved a higher diagnostic yield for lesions ≤ 20 mm (p = 0.005), whereas no yield advantage was observed for lesions > 20 mm. Additionally, diagnostic yield did not significantly differ between groups when stratified by lesion pathology (malignant vs. benign), lobar location, distance from the hilum, or presence of a bronchus sign. Complication rates were comparable across both groups, with pneumothorax and hemorrhage being the most common adverse events. The authors concluded that VBNA does not significantly improve overall diagnostic yield compared with NVBNA bronchoscopy for PPLs but may offer advantages for smaller lesions (≤ 20 mm) and reduced overall procedure time.

***Non-Randomized Studies, Retrospective Reviews, and Other Evidence***

Hiddinga et al. (2023) reported results from the first cohort of the NAVIGATOR study, a single-center, prospective, observational cohort study designed to evaluate the performance of virtual navigation bronchoscopy (VNB) for obtaining a pathological diagnosis of solitary pulmonary nodules in a real-world clinical setting. A total of 35 patients underwent VNB for pulmonary nodules that were considered inaccessible using conventional approaches or for which alternative diagnostic procedures were deemed less effective of less safe. Eligible patients were adults aged ≥18 years with one or more pulmonary nodules measuring >6 mm in diameter, located more than 5 mm from the parietal pleura and within the lung parenchyma, and assessed as technically accessible by VNB. Exclusion criteria included contraindications to bronchoscopy, inability to discontinue anticoagulant or antiplatelet therapy, pregnancy or breastfeeding, moderate to severe pulmonary fibrosis, and severe emphysema with bullae >5 cm near the target nodule or navigation tunnel. All patients underwent high-resolution computed tomography prior to the VNB procedure. The medium patient age was 68 years (range 45–80), with an almost equal distribution of male (n=18) and female (n=17) participants. Fifteen patients had no prior history of solid malignancy, thirteen had a history of non-lung solid malignancy, and seven were undergoing evaluation for recurrence or progression of previously diagnosed lunch cancer. Prior diagnostic procedures had been performed in 13 patients, including diagnostic bronchoscopy, EBUS-guided fine-needle aspiration, endoscopic ultrasound-guided fine-needle aspiration, computed tomography–guided transthoracic biopsy, and thoracoscopy. Most pulmonary nodules were solid (n=33), with one subsolid lesion and one ground-glass opacity. Twelve nodules measured ≤20 mm, while 23 measured >20 mm, with a median lesion size of 25 mm (range 10–57 mm). A bronchus sign was identified in 22 nodules. The overall diagnostic yield was 77%, with yield strongly influenced by lesion size and navigation pathway. Diagnostic yield was highest for lesions with an airway path identified on CT imaging (89%; 15 of 18 lesions) and for nodules >20 mm in diameter (78%; 18 of 23 lesions). In contrast, diagnostic yield for nodules ≤20 mm was substantially lower at 37%, and yield for lesions accessed using a tunnel pathway was 62%. A definitive diagnosis was obtained in 27 cases, including 22 malignant and five benign lesions. Adverse events were reported in 10 patients, predominantly consisting of hemorrhage (n=9), with only two cases classified as grade 3 bleeding requiring additional bronchoscopic hemostasis. One patient experienced self-limited subcutaneous emphysema of the neck three days after the procedure. The authors concluded that the performance of this initial VNB cohort was comparable to previously published studies and noted that enrollment is ongoing to strengthen the robustness of the study findings.

## Electromagnetic Navigation Bronchoscopy (ENB)

***Randomized Controlled Trials***

Bondue et al. (2023) conducted a single-center, prospective RCT comparing the diagnostic yield of electromagnetic navigation bronchoscopy (ENB) performed with cone-beam computed tomography (CBCT) versus ENB performed

under standard X-ray fluoroscopy in a traditional endoscopy suite. The study enrolled adult patients with pulmonary nodules measuring ≤ 30 mm who required biopsy, with 49 patients randomized between the two study arms. In both groups, ENB was performed in conjunction with fluoroscopic guidance and radial endobronchial ultrasound (rEBUS), followed by six transbronchial forceps biopsies and one transbronchial lung cryobiopsy unless deemed unnecessary by the proceduralist. ENB procedures performed under CBCT guidance demonstrated a significantly higher diagnostic yield compared with those performed using standard fluoroscopic guidance endoscopy suite (80% vs. 42%, respectively; p = 0.023). Adverse events were minimal and comparable between groups, with pneumothorax occurring in three patients (6%) overall; all bleeding events were classified as mild to moderate. The authors concluded that ENB guided by CBCT significantly improves diagnostic yield and accuracy for small pulmonary nodules compared with standard fluoroscopic guidance. The trial was registered with ClinicalTrials.gov (NCT05257382).

Zheng et al. (2022) conducted a prospective, multicenter, RCT to evaluate the diagnostic efficacy and safety of a novel ENB system used in conjunction with endobronchial ultrasound and a guide sheath (EBUS-GS), compared with EBUS-GS alone, for diagnosing peripheral pulmonary nodules (PPNs). A total of 400 participants were enrolled, with 385 included in the final analysis. Participants were adults with PPNs suspicious for malignancy between 8 mm and 30 mm in diameter, with lesions located beyond the segmental bronchi and not visible on standard bronchoscopy. The primary outcome was diagnostic yield, defined as the proportion of patients in whom bronchoscopy yielded a definitive diagnosis that matched the final clinical or surgical diagnosis. Diagnostic yield was significantly higher in the ENB-EBUS-GS group at 82.9% compared to 73.4% in the EBUS-GS only group, with an adjusted difference of 9.0%. Diagnostic yield was higher for malignant lesions (90.3% vs. 78.7%) and for nodules with a bronchus sign leading to the lesion on CT. ENB-EBUS-GS required significantly less time to locate lesions (213.2 ± 145.6 seconds) than the EBUS-GS group (264.8 ± 189.5 seconds; p = 0.003). However, there was no statistically significant difference in the total procedure time between groups. Adverse events were comparable between groups, with moderate intraoperative hemorrhage occurring in 3.6% of patients in the ENB-EBUS-GS group and 3.1% in the EBUS-GS group. No patients required additional intervention. Multivariate analysis identified lesion nature (malignant vs. benign), presence of a bronchus sign, type of anesthesia, and group assignment as significant factors influencing diagnostic success. The authors concluded that the addition of the novel ENB system to EBUS-GS significantly improves the diagnostic yield for PPNs without increasing complication rates. The RCT was registered with ClinicalTrials.gov (NCT03569306).

***Systematic Reviews and Meta-Analyses***

Folch et al. (2020) conducted a systematic review and meta-analysis to evaluate the diagnostic performance and safety of ENB for PPLs suspected of lung cancer. The review included 40 studies comprising 3,342 participants. Outcomes assessed included the sensitivity of ENB for malignancy detection, adequacy of tissue sampling for ancillary testing, and procedure-related complications. The pooled sensitivity of ENB for diagnosing malignancy was 77%, with substantial heterogeneity ($I^2$ = 80.6%). Specificity was 100% (95% CI: 99-100%; $I^2$ = 0%), and overall diagnostic accuracy was high. ENB successfully obtained adequate tissue for ancillary testing in 90.9% of cases (95% CI: 84.8%-96.9%; $I^2$ = 80.7%). The pooled pneumothorax rate was low at 2.0% (95% CI: 1.0-3.0%; $I^2$ = 45.2%). The authors concluded that ENB is a safe modality with good sensitivity for diagnosing malignancy in patients with PPLs. However, the generalizability of the results is limited due to high heterogeneity and predominant use of a single device platform (superDimension navigation system) across most studies.

McGuire et al. (2020) conducted a systematic review and meta-analysis comparing the diagnostic accuracy, sensitivity for malignancy, and safety of rEBUS versus ENB for sampling PPLs identified on chest CT. The analysis included 41 studies, encompassing 3,204 patients and 2,988 lesions (2,102 rEBUS; 886 ENB). The pooled sensitivity for detecting cancer was 70.7% (95% CI: 67.2-74.0), with nearly identical results for rEBUS at 70.5% (95% CI: 66.1-74.8) and ENB at 70.7% (95% CI: 64.7-76.8). Pooled diagnostic accuracy was 74.2% (95% CI: 71.0-77.3) with similar performance results for rEBUS (72.4%) and ENB (76.4%). Both modalities demonstrated comparable safety profiles with overall complication rates < 2%. The authors concluded that both rEBUS and ENB provide similar sensitivity and accuracy for PPL diagnosis and achieve high rates of lesion localization.

Qian et al. (2020) performed a meta-analysis comparing ENB with VNB for diagnosing pulmonary nodules. The meta-analysis included 32 studies (16 ENB; 16 VNB) with a total of 1,981 patients. ENB demonstrated higher specificity (0.81 vs. 0.65), while sensitivity was similar between ENB and VNB (0.80 vs. 0.80). ENB showed improved detection performance for larger lesions. The authors noted the absence of randomized controlled trials directly comparing ENB and VNB as a key limitation.

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***Non-Randomized Studies, Retrospective Reviews, and Other Evidence***
Yutaka et al. (2022) performed a retrospective comparison of ENB-guided versus VNB-guided transbronchial lung biopsies at a single institution. The analysis included 100 ENB cases and 50 VNB cases. Diagnostic yield was higher in the ENB group than in the VNB group (64.0% vs 46.0%). A positive bronchus sign was identified as a key factor associated with successful diagnosis An 81.0% diagnostic yield was noted in ENB with positive bronchus sign compared to a 60.0% diagnostic yield in VNB.

Folch et al. (2019) conducted the NAVIGATE study, a prospective, multicenter cohort study evaluating ENB using the superDimension navigation system. The study enrolled 1215 participants across 29 centers, with eligibility determine by physician discretion rather than protocol-mandated criteria. Procedural techniques, imaging modalities, and biopsy tools were selected according to local practice, including lymph node staging with endobronchial ultrasound as deemed appropriate. Fluoroscopy was used in the majority of cases, and radial probe EBUS was used in more than half. Among the 1,157 patients who underwent lung lesion biopsy, tissue acquisition was successful in 94.4%. Follow-up was post-ENB was completed at 1 month in 98.9% of participants and at 12 months in 80.3% of participants. The 12-month diagnostic yield was 73%, aligning with previously reported ENB yields ranging from 65% to 73%.

## Robotic-Assisted Bronchoscopy (RAB)

***Systematic Reviews and Meta-Analyses***
Zhang et al. (2024) conducted a systematic review and meta-analysis evaluating the diagnostic yield and safety of robotic-assisted bronchoscopy (RAB) for PPLs. Ten studies were included - five prospective studies and five retrospective studies – utilizing either the Ion or Monarch RAB platforms, encompassing 725 lesions. The pooled diagnostic yield was 80.4% with individual study yields ranging from 70% to 90%. The overall complication rate was low at 3% with pneumothorax being the most frequently reported adverse event. No procedure-realted deaths were reported. Subgroup analyses demonstrated higher diagnostic yields in lesions larger than 30 mm, in lesions with an identifiable bronchus sign, and when a concentric radial EBUS view was achieved. Lesions measuring 20 mm or smaller had a pooled diagnostic yield of 78.0%, exceeding historical outcomes reported for earlier guided bronchoscopy techniques.

Ali et al. (2023) performed a systematic review and meta-analysis examining the diagnostic performance and safety profile of RAB. Twenty-five studies were included, compromising both prospective and retrospective designs, resulting in moderate to high heterogeneity. Across 1,779 analyzed lesions, the pooled diagnostic yield was 84.3%. Higher diagnostic yield was associated with larger lesion size, presence of bronchus sign, and attainment of a concentric radial EBUS view during the procedure. Adverse event rates were low, with pneumothorax occurring in 2.3% of cases and chest tube placement required in 1.2%. Significant hemorrhage occurred in 0.5% of cases. Researchers concluded that RAB had the potential to improve diagnostic yield compared with conventional navigational bronchoscopy techniques such as ENB, although well-designed prospective comparative trials are necessary to clarify the independent contribution of RAB and procedural variables to diagnostic outcomes.

***Non-Randomized Studies, Retrospective Reviews, and Other Evidence***
Khan et al. (2023) completed a retrospective analysis evaluating RAB performed at three community hospitals using the Monarch platform. The analysis included 264 patients aged 21 years or older. The median patient age was 69.5 years, with a predominance of female patients. Over half had chronic obstructive pulmonary disease, and nearly half had a high pre-procedure probability of malignancy. Most patients had a single lesion, with a median lesion size of 19.3 mm, and the majority of lesions were located in the peripheral outer lung. Diagnostic yield was assessed at the time of the index procedure and again using outcomes from 12-month clinical follow-up. Tissue sampling was successful in nearly all cases, with malignancy diagnosed in 43.6%, most commonly adenocarcinoma. Diagnostic yield varied widely depending on the definition used but remained high overall. Complications occurred in 20 patients, most often pneumothorax, with chest tube placement required in ten cases. Pneumothorax rates were notably higher when procedures were performed by thoracic surgeons compared with interventional pulmonologists. Bleeding events were infrequent but required intervention in all affected cases. The authors concluded that RAB achieved high diagnostic yield in real-world community practice, even in a population with challenging lesion characteristics, and recommended further comparative studies across bronchoscopic platforms.

Chen et al. (2021) conducted a prospective, multicenter pilot and feasibility study evaluating RAB combined with radial probe EBUS for PPLs. Standard flexible bronchoscopy preceded robotic navigation to exclude endobronchial disease. Lesions ranged from 1 to 5 cm, with a median size of 2.3 cm. Of the 55 enrolled patients, 53 were included in the final

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analysis. Lesion localization was successful in over 96% of cases, and diagnostic yield was approximately 74.1%, higher than rates historically reported for conventional guided bronchoscopy. Adverse events occurred in fewer than 4% of patients and were comparable to standard bronchoscopy. The authors indicated that larger prospective studies are needed to confirm these findings.

### Bronchoscopic Technique Comparisons

Kops et al. (2023) completed a systematic review and meta-analysis to determine the diagnostic yield and safety of the available types of navigation bronchoscopy. The analysis included 95 studies involving a total of 10,381 patients and 10,682 lesions. Many included studies demonstrated methodological limitations, particularly related to diagnostic yield definitions and follow-up timing. The pooled diagnostic yield across all navigation modalities was 70.9%. When stratified by technique, median diagnostic yield was 70,3% for electromagnetic navigation bronchoscopy, 69.4% for virtual navigation bronchoscopy, 76.5% for robotic-assisted bronchoscopy, 78.2% for cone-beam computed tomography (CBCT), and 77.4% for CBCT multimodality approaches, with no statistically significant difference among techniques ($p = 0.0091$). Diagnostic yield was significantly higher for newer navigation technologies compared with longer-established techniques, with median yields of 77.5% and 68.6% respectively ($p < 0.001$). The presence of a bronchus sign and larger lesion size were consistently associated with higher diagnostic yield, while results varied depending on how diagnostic yield was defined and reported. Adverse event rates were low and comparable across navigation techniques, with pneumothorax being the most common complication. The authors concluded that navigational bronchoscopy is generally safe and capable of achieving moderate to high diagnostic yield, particularly with newer technologies; however, substantial heterogeneity across studies limits direct comparisons and definitive conclusions regarding superiority among modalities.

Tsai et al. (2023) conducted a single-center retrospective study comparing ENB and VNB for lesions of unknown origin. Thirty-five patients were included, with 19 undergoing ENB and 16 undergoing VNB. Eligible participants were at least 18 years of age, had pulmonary lesions that remained undiagnosed after interdisciplinary evaluation, and were considered appropriate candidates for navigation bronchoscopy. All procedures were performed in accordance with the manufacturers' instructions for each navigation system. ENB procedures were performed without adjunctive fluoroscopy, radial EBUS, or additional sampling techniques such as cytology brushing or bronchoalveolar lavage. The mean distance from the lesions to the pleural space was 16.1±11.7mm (range 1.0-41.0mm) and most lesions demonstrated a positive air-bronchus sign. Navigation success was higher in the VNB group than in the ENB group (93.8% vs. 78.9%). No procedure complications or mortality were reported. The authors concluded that VNB represents a feasible alternative to ENB for lesion navigation and suggested that the use of cone-beam CT may further enhance navigation success regardless of bronchus sign status. However, interpretation of the results is limited by the small sample size and the fact that all VNB procedures were performed by a single operator, introductive for operator-related bias.

### National/Specialty Organizations

The **Scottish Intercollegiate Guidelines Network (SIGN)** (2014), in a National Clinical *Guideline (No. 137) for the Management of Lung Cancer*, note that flexible bronchoscopy has a lower diagnostic sensitivity for peripheral lesions compared with central lesions. Even though fluoroscopy may improve the diagnostic yield, results are still poor compared to percutaneous fine needle aspiration (FNA) biopsy. Advanced bronchoscopic techniques, such as VBN or EBN, may have a role in obtaining diagnostic material from primary tumors in some patients, but there is insufficient evidence that it provides a higher diagnostic yield than traditional image guidance approaches and fiber optic bronchoscopy. The guideline emphasizes that percutaneous FNA biopsy should be considered as the preferred diagnostic technique in patients with peripheral lesions. The use of advanced bronchoscopic techniques should be considered in patients with tumors where sampling with traditional approaches has failed to provide sufficient diagnostic material.

The **American College of Chest Physicians (ACCP)** published *Diagnosis and Management of Lung Cancer: Evidence-Based Clinical Practice Guidelines, 3rd ed.* (Rivera et al. 2013). In patients suspected of having small cell lung cancer based on the radiographic and clinical findings, it's recommended that the diagnosis be confirmed by the least invasive method (e.g., sputum cytology, thoracentesis, fine needle aspiration, bronchoscopy) as dictated by the patient's presentation. 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. The procedure can be performed with or without fluoroscopic guidance and may be performed with radial probe ultrasound. If electromagnetic navigation is not available, transthoracic needle aspiration is recommended.

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## CODING & BILLING INFORMATION

### CPT (Current Procedural Terminology)

| Code | Description |
|---|---|
| **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]) |

### HCPCS (Healthcare Common Procedure Coding System)

| Code | Description |
|---|---|
| **C7509** | Bronchoscopy, rigid or flexible, diagnostic with cell washing(s) when performed, with computer-assisted image-guided navigation, including fluoroscopic guidance when performed |
| **C7510** | Bronchoscopy, rigid or flexible, with bronchial alveolar lavage(s), with computer-assisted image-guided navigation, including fluoroscopic guidance when performed |
| **C7511** | Bronchoscopy, rigid or flexible, with single or multiple bronchial or endobronchial biopsy(ies), single or multiple sites, with computer-assisted image-guided navigation, including fluoroscopic guidance when performed |

**CODING DISCLAIMER:** Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

## APPROVAL HISTORY

| | |
|---|---|
| **06/10/2026** | Policy reviewed, no changes to coverage criteria. |
| **06/11/2025** | Policy reviewed, no changes to coverage criteria. |
| **06/12/2024** | Policy reviewed, no changes to criteria. |
| **06/14/2023** | Policy reviewed, changes to coverage criteria include electromagnetic bronchoscopy now medically necessary and inclusion of robotic-assisted bronchoscopy as experimental/investigational/unproven. Updated Overview, Summary of Medical Evidence, and References. Formatting updates to Disclaimer section and "Documentation Requirements" disclaimer in Coverage Policy section. Supplemental Information section removed. Codes C7509, C7510, and C7511 added. Policy reviewed on May 12, 2023, by a practicing, board-certified physician in the areas of Pulmonary Disease, Critical Care, and Internal Medicine. |
| **06/08/2022** | Policy reviewed, no changes. |
| **06/09/2021** | Policy reviewed, no changes. |
| **06/17/2020** | Policy reviewed, no changes, updated references. |
| **06/19/2019** | Policy reviewed, no changes, updated references. |
| **07/10/2018** | Policy reviewed, no changes. |
| **09/19/2017** | Policy reviewed, no changes. |
| **09/15/2016** | Policy reviewed, no changes. |
| **12/16/2015** | Policy reviewed, no changes. |
| **08/25/2014** | New policy. |

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