Molina Clinical Policy
Image-Guided Bronchoscopy for Evaluation of Peripheral Pulmonary Lesions: Policy No. 206

Last Approval: 6/12/2024
Next Review Due By: June 2025

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

Image-guided bronchoscopy consists of several techniques, such as virtual navigation bronchoscopy, electromagnetic navigation bronchoscopy, and robotic-assisted bronchoscopy that are used to biopsy peripheral pulmonary lesions that are located in the lung periphery. The primary goal of using image-guided bronchoscopy is to serve as an additional "tool" in the biopsy of peripheral pulmonary lesions as these lesions are either difficult to reach or difficult to biopsy using conventional flexible bronchoscopy alone (Shepherd 2024).

Virtual navigation bronchoscopy (VNB) is a non-invasive method of generating three-dimensional images of the tracheobronchial tree that extend out to the seventh generation of airways. The three-dimensional images are created using computed tomography scans obtained using VNB device manufacturer specific protocols for imaging. A primary benefit of VNB is that it "may be able to provide important information about the condition of the distal airway beyond an obstruction when a flexible bronchoscope cannot pass an obstructing airway lesion." In addition, VNB can provide information about the location of other structures, such as lymph nodes or blood vessels, that surround the airways (Islam 2023).

Electromagnetic navigation bronchoscopy (ENB) is similar to VNB in that three-dimensional images of the tracheobronchial tree are created using computed tomography scans using manufacturer-specific protocols for imaging. However, ENB systems also uses an electromagnetic field board or generator that allows for real-time tracking of tools during the guidance and biopsy phases of the procedure. A special catheter "with a sensor probe is inserted into the working channel of a regular flexible bronchoscope…[and] then steered through the distal airways beyond the third generation of airways." ENB systems are limited in that they cannot directly visualize the lesion. Due to this, radial probe endobronchial ultrasound (EBUS) is often used in conjunction with ENB to verify the lesion location. Using radial probe EBUS in conjunction with ENB may increase the diagnostic yield (Shepherd 2024; Islam 2023).

The primary difference between VNB and ENB systems is that ENB systems operate similar to a global positioning system with "directions" to the lesion while VNB systems are similar to a map. VNB systems are typically used before a procedure to plan a path to the lesion. ENB systems have the ability to allow the operator to plan a path while also suggesting an alternative path (Shepherd 2024; Islam 2023).

Robotic-assisted bronchoscopy (RAB) is a newer image-guided bronchoscopy technique that involves using a robotic platform, similar to those used during robotic surgeries, to control a catheter as it is navigated through the airways without requiring the operator to directly touch the bronchoscope. The catheter used for navigation is smaller than a bronchoscope, allowing for navigation to the much smaller airways that are not normally accessible by bronchoscope. Another benefit of using a RAB system is the ability to lock the catheter in place once the lesion is reached. There are currently two RAB systems available with both requiring thin-slice computed tomography scans (similar to VNB) and one system utilizing an electromagnetic field similar to ENB. Two important limitations for the currently available RAB systems include a lack of "tactile feedback to the operator [for both systems] and one system does not offer actual visualization at the time of biopsy (Shepherd 2024)." Secondary confirmation of correct placement can also be confirmed using radial probe EBUS, fluoroscopy, and cone-beam computed tomography (Islam 2023).

COVERAGE POLICY

Electromagnetic Navigational Bronchoscopy is 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 may be performed in conjunction with Electromagnetic Navigational Bronchoscopy to diagnose and stage lung cancer.

Virtual navigation bronchoscopy and robotic-assisted bronchoscopy for the evaluation of pulmonary lesions **is considered investigational, experimental, and unproven** due to insufficient evidence published in the peer-reviewed medical literature.

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

Hiddinga et al. (2023) reported on the first cohort of the NAVIGATOR single-center, prospective, observational cohort study. The goal of the NAVIGATOR study is “to evaluate the performance of [VNB] to obtain a diagnosis of [solitary pulmonary nodules] in a real-world clinical setting.” A total of 35 patients underwent a VNB procedure for pulmonary nodules “that were not otherwise accessible or for which other diagnostic procedures were considered less successful or less safe.” Inclusion criteria included age > 18 years with a pulmonary nodule or nodules with a diameter > 6 mm and located > 5 mm from the parietal pleura and within the parenchymal tissue. Nodules also had to be considered accessible by VNB. Exclusion criteria included any contraindication to a bronchoscopic procedure, inability to stop anticoagulant or antiplatelet medications, pregnant or breastfeeding women, moderate to severe pulmonary fibrosis, and severe emphysema with bullae > 5 cm in the vicinity of the target nodule or tunnel. All eligible patients received a high-resolution computed tomography scan before undergoing the VNB. Results showed a median age of 68 years (range 45-80 years) with 18 male patients and 17 female patients. Approximately 15 patients underwent VNB for a pulmonary nodule without a history of solid malignancy, 13 had a history of solid malignancy other than lung cancer, and 7 were being considered for a relapse or progression of prior lung cancer. A total of 13 patients underwent a diagnostic procedure before undergoing a VNB (n = 9 diagnostic bronchoscopy; n = 2 EBUS with fine needle aspiration; n = 1 endoscopic ultrasound with fine needle aspiration; n = 3 computed tomography-guided transthoracic biopsy; n = 1 thoracoscopy). In terms of pulmonary nodule morphology, 33 were solid, one was subsolid, and one was ground glass opacity. Approximately 12 pulmonary nodules were ≤ 20 mm in diameter and 23 were > 20 mm in diameter and the median nodule size was 25 mm (range 10-57 mm). A visible bronchus sign was present in 22 nodules. The overall diagnostic yield was 77% with yield being “dependent on [pulmonary nodule] size and chosen path, with highest yield in lesions with an airway path on [computed tomography] imaging 89% (15/18 lesions), and 78% in [pulmonary nodules] with a diameter > 20 mm (18/23 lesions).” Of note, median diagnostic yield for nodules with a diameter ≤ 20 mm was only 37% and those with a tunnel path was 62%. A diagnosis was obtained in 27 cases with 22 of those being malignant and five being benign. Adverse events occurred in a total of 10 patients with hemorrhage occurring in nine patients and one case of self-limiting subcutaneous emphysema in the neck region three days after the VNB procedure. Of those that experienced hemorrhage, only two experienced grade 3 hemorrhage that required additional bronchoscopic hemostasis. Researchers noted that “the performance of [the] first cohort of VNB procedures was comparable to other studies.” Researchers plan to continue the study with additional patients to make the data more robust.

A meta-analysis completed by Jiang et al. (2020) found diagnostic yield to be approximately 1.69 times higher in VNB-assisted groups. Jiang et al. (2020) also found diagnostic yield to be affected by the location, size of the lesion, and the experience of the clinician performing the bronchoscopy. Diagnostic yields were noted to be higher in the upper lobes and peripheral third lung, particularly when peripheral pulmonary lesion size was ≤ 20 mm.

Another systematic review and meta-analysis completed by Shen et al. (2021) found that diagnostic yield was similar in VNB-assisted and non-VNB-assisted groups. A sub-analysis of data found that the diagnostic yield was higher in the VNB-assisted group when peripheral pulmonary lesion size was ≤ 20 mm. It was also noted that the total examination time was significantly shorter in the VNB-assisted group despite similar diagnostic yields. Other factors noted to impact diagnostic yield were related to VNB software utilized for reconstructing the airways.

Giri et al. (2022) also completed a review of 6 randomized controlled trials comparing VNB-assisted to non-VNB-assisted and other forms of guided bronchoscopy. One randomized controlled trial included in the review found no significant difference in diagnostic yield between VNB-assisted and non-VNB-assisted groups. Another randomized controlled trial compared VNB-assisted to x-ray fluoroscopy-assisted groups and found no significant difference in diagnostic yield. Another randomized controlled trial of 1,010 participants compared VNB-assisted to other forms of guided bronchoscopy. It was noted that VNB combined with endobronchial ultrasound (EBUS) produced higher diagnostic yields. However, it was also noted that there was no significant difference in diagnostic yield between VNB combined with EBUS and standard EBUS. Overall data showed a higher diagnostic yield when peripheral pulmonary lesion size was > 20 mm.

Electromagnetic Navigation Bronchoscopy

Kim et al. (2023) completed a retrospective analysis to determine the diagnostic accuracy and safety of ENB with transthoracic needle biopsy. A total of 32 patients were enrolled at a single center in South Korea. Inclusion criteria included adults aged ≥ 18 years with a peripheral pulmonary lesion ≥ 10mm that was “accessible by an anterior or lateral chest percutaneous approach.” The Veran SPiNperc System was used for all procedures. Bronchoscopy instruments (e.g., introducer needle, biopsy needle) were the same size for every procedure. Outcomes measured included the mean size of pulmonary lesions, the median distance from the pleura, the diagnostic accuracy, pathological outcomes, and adverse events. The introducer needle was passed only once in all cases. Mean pulmonary lesion size was 36.9±17.4mm with six patients having a lesion 10-20mm in size, six patients having a lesion 21-30mm in size, and 20 patients having a lesion > 30mm in size. The median distance from the pleura was 15.5mm with the right upper and left lower lobes being the most prevalent locations of lesions. A total of 14 patients were diagnosed with a malignant lesion (adenocarcinoma = 12, squamous cell carcinoma = 1, small cell lung cancer = 1). Eighteen of the cases were initially determined to be negative, but further analysis following the procedure revealed that seven of those cases were false negatives (squamous cell carcinoma = 3, adenocarcinoma = 3, metastatic carcinoma from colorectal cancer = 1). The total diagnostic accuracy was 75.0% with a diagnostic yield for lung cancer 66.7% (excluding false negatives) and 50% (including false negatives). Sensitivity was 66.7% (excluding false negative cases) with a low estimate of 56.0% and a high estimate of 66.7%. The specificity was 100% at all points (excluding false negatives and low and high estimates). The only reported adverse event was one case of hemoptysis. Researchers determined that the diagnostic accuracy and rate of adverse events demonstrated in this study were similar to other studies, adding further evidence to support the safety and efficacy of ENB.

Folch et al. (2019) completed the NAVIGATE study, a prospective, multicenter, cohort study evaluating ENB using the superDimension navigation system. A total of 1215 participants were enrolled at 29 participating sites between April 2015 and August 2016. Individual physician judgement was utilized in determining candidacy for an elective ENB and there were no protocol-specified restrictions for tools, imaging, or procedural technique, including completion of a lymph node staging EBUS before, during, or after ENB. Fluoroscopy was noted to be used in 91% of cases and radial probe EBUS in 57% of cases. Approximately 1157 participants underwent lung lesion biopsy and tissue was successfully obtained in 94.4% of those participants. Follow-up 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 noted to be 73%, consistent with other published estimates of 65% to 73%.

Qian et al. (2020) completed a meta-analysis to compare the diagnostic yield of ENB to VNB. The meta-analysis included 32 studies (16 each for ENB and VNB) with a total of 1981 patients. The meta-analysis revealed that ENB had an advantage over VNB in terms of specificity (0.81 vs 0.65). There were no differences noted between sensitivity (0.80 vs 0.80). It was noted that ENB had a higher detection ability with larger lesions. Limitations that

were noted in the meta-analysis were the lack of RCTs comparing ENB to VNB.

Yutaka et al. (2022) completed a retrospective study to compare the results of ENB transbronchial lung biopsies to VNB transbronchial lung biopsies at a single institution. The study included 100 ENB samples and 50 VNB samples. Overall results showed improved diagnostic yield in ENB as compared to VNB (64.0% vs 46.0%). A positive bronchus sign was a significant factor in successful diagnostic yield. An 81.0% diagnostic yield was noted in ENB with positive bronchus sign compared to a 60.0% diagnostic yield in VNB.

Robotic-Assisted Bronchoscopy

Khan et al. (2023) completed a retrospective analysis of patients that underwent a RAB at three community hospitals between January 2019 and March 2020. All procedures were performed using the Monarch Platform. Patients were included in analysis if they were ≥ 21 years of age. A total of 264 patients were included in the analysis. Primary pulmonary lesion characteristics were collected and the characteristics of one secondary lesion were collected if applicable. "Diagnostic yield was calculated at the index RAB and using 12-month follow-up data. At index, all malignant and benign (specific and non-specific) diagnoses were considered diagnostic. After 12 months, benign non-specific cases were considered diagnostic only when follow-up data corroborated the benign result. An alternative definition at index classified benign non-specific results as non-diagnostic, while an alternative 12-month definition categorized index non-diagnostic cases as diagnostic if no malignancy was diagnosed during follow-up." Results showed a median patient age of 69.5±10.5 years. Approximately 56.8% of patients were female, 11% had a history of lung cancer, and 52% had chronic obstructive pulmonary disease. Of note, 62.5% of patients had a single lesion (range 1-22 lesions) and 48.2% of "patients had a pre-procedure probability of malignancy ≥ 65%." A total of 264 primary and 48 secondary lesions were biopsied with a median lesion size of 19.3 mm. Approximately 58.9% of lesions were located in the peripheral outer third of the lung and 22% of primary lesions were subsolid. "Tissue samples were successfully obtained at the index RAB procedure in all but one case, which was classified as non-diagnostic [and] the index RAB procedure led to a malignant diagnosis in 115 patients (43.6%)" with the most common diagnosis being adenocarcinoma (46.1%). Overall diagnostic yield at index procedure was 85.2% (range 80.9-89.5%) and at 12-months was 79.4% (range 74.4-84.3%) using the first definition of diagnostic yield. The diagnostic yield for the index procedure was 58.7% (range 52.8-64.7%) and 89.0% (range 85.1-92.8%) at 12-months using the alternative definition of diagnostic yield. A total of 20 patients had device- or procedure-related complications with the most common being pneumothorax (n= 15). Ten of the patients that developed a pneumothorax required chest tube placement. Researchers noted that the rate of pneumothorax was much higher when the RAB procedure was completed by a thoracic surgeon (15.8%) versus an interventional pulmonologist (4.0%). Bleeding occurred in four patients and all four patients required treatment to stop the bleeding. Researchers noted that this study "demonstrated a high diagnostic yield…despite representing a real-world community population with a relatively low pre-procedure probability of malignancy and where traditionally challenging lesions, such as those < 20 mm, peripherally located, and without a bronchus sign on [computed tomography] scan, were in the majority." Researchers recommended additional studies comparing diagnostic yields across bronchoscopic technologies.

Ali et al. (2023) completed a systematic review and meta-analysis "to determine the diagnostic performance and safety profile of RAB." A total of 25 studies were included with 20 studies including both diagnostic and safety analyses and 5 studies only reporting safety analyses. The included studies were a mix of prospective and retrospective studies and different RAB systems, leading to high heterogeneity (I^2 = 65.6%). A total of 1779 lesions were included in analyses across all 20 studies with a pooled diagnostic yield of 84.3%. Increased diagnostic yield was noted when lesion size was > 2 cm, there was a positive bronchus sign, and a concentric radial EBUS view was used in conjunction with RAB. Adverse event rates were comparable with pneumothorax occurring in 2.3% of cases and 1.2% of cases requiring a chest tube for treatment of pneumothorax. Significant hemorrhage occurred in 0.5% of cases. Researchers concluded that RAB can significantly [increase] the diagnostic yield of navigational bronchoscopy compared [to] conventional systems such as [ENB], but well-designed prospective studies are needed to better understand the impact of various factors…on the diagnostic yield of RAB."

Chen et al. (2021) completed a prospective, multicenter pilot and feasibility study to determine the safety and feasibility of RAB with radial probe EBUS in patients with peripheral pulmonary lesions. The primary goals of the study were to determine the localization and adverse event rates. A standard flexible bronchoscopy was performed prior to RAB with radial probe EBUS to exclude the presence of endobronchial disease and to provide topical anesthesia based on the discretion of the bronchoscopist. Peripheral pulmonary lesion size in the study ranged from 1 to 5 cm with a median

size of 2.3 cm. The study initially enrolled 55 patients. However, one patient withdrew study consent and EBUS imaging was only available in 53 cases, leaving 53 cases for inclusion. Lesion localization was achieved in 96.2% of cases and diagnostic yield was approximately 74.1%. Researchers noted this is higher than the diagnostic yield of 40% to 60% in other guided bronchoscopic approaches. Adverse events occurred in 3.7% of cases which is comparable to standard bronchoscopy. Larger prospective studies are needed to confirm the results of this study.

Bronchoscopic Technique Comparison

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. A total of 95 studies were included with a total of 10,381 patients and 10,682 lesions. Of the 95 included studies, 63 were found to have a "high risk of bias or applicability concerns in at least one domain…[with] most risk of bias…found in the 'flow and timing' for diagnostic yield (n = 47 studies)." Subgroup analysis was completed by comparing navigation type (ENM, VNB, RAB, cone beam computed tomography [CBCT], and CBCT multimodality), length of time the navigation technique had been established (recent or longer established), strictness of definition of diagnostic yield (strict, intermediate, liberal, not reported), median nodule size (< 20 mm or ≥ 20 mm), publication year (before 2012 or after 2012), and additional navigation tools in ENB (no additional tools, additional tools, or tomosynthesis guided ENB). Further explorative subgroup analysis was completed by comparing individual nodule size (< 20 mm or ≥ 20 mm) and bronchus sign (positive or negative). The overall diagnostic yield was 70.9%. Diagnostic yield for ENB was 70.3% (n = 5669, range 66.0-74.2%), VNB was 69.4% (n = 3628, range 65.3-73.2%), RAB was 76.5% (n = 558, range 68.4-82.9%), CBCT was 78.2% (n = 371, range 71.5-83.7%), and CBCT multimodality was 77.4% (n = 456, range 70.7-82.9%) (p = 0.091). Median diagnostic yield for recent navigation techniques was 77.5% (n = 1926, range 74.7-80.1%) and longer established navigation techniques was 68.8% (n = 8756, range 65.9-71.6%) (p < 0.001). The median diagnostic yield based on the strictness of the definition of diagnostic yield was 67.6% for "strict," 72.9% for "intermediate," 70.7% for "liberal," and 72.4% for "not reported" (p = 0.255). When comparing median nodule size, median diagnostic yield was 72.1% (range 67.2-76.6%) for nodules < 20 mm (n = 2843) and 70.4% (range 67.5-73.2%) for nodules ≥ 20 mm (n = 7839) (p = 0.506). These results differed when comparing individual nodule size in explorative subgroup analysis as an individual nodule size ≥ 20 mm produced a median diagnostic yield of 79.4% (n = 3744, range 76.0-82.4%) compared to a median diagnostic yield of 67.4% (n = 3499, range 63.1-71.5%) when individual nodule size was < 20 mm (p < 0.001). Based on publication year, median diagnostic yield was 73.9% (n = 1489, range 69.0-78.3%) for studies before 2012 and 70.2% (n = 9193, range 67.3-72.9%) for studies after 2012 (p = 0.254). Median diagnostic yield was improved with the use of additional navigation tools (70.9%, n = 3109, range 63.5-77.4%) and tomosynthesis-guided ENB (79.5%, n = 541, range 65.4-88.8%) compared to no additional navigation tools (64.0%, n = 1508, range 61.8-73.1%) (p = 0.154). A positive bronchus sign produced a much higher median diagnostic yield (73.7%, n = 3302, range 69.4-77.6%) compared to a negative bronchus sign (54.1%, n = 1826, range 48.5-59.6%) (p < 0.001). The overall adverse event rate was 5.6% (n = 547) with the most common adverse event being pneumothorax (n = 246) with 115 of those patients requiring intervention. Bleeding was another common adverse event and occurred in approximately 205 patients. Less common adverse events included pneumonia/infection (n = 17), respiratory insufficiency/hypoxemia (n = 31), arrhythmia (n = 2), minor complaints such as headache or nausea (n = 37), and other (n = 8). The overall rates of adverse events were similar in all navigation techniques with a rate of 6.3% for ENB, 4.8% for VNB, 5.7% for RAB, and 4.0% for CBCT and CBCT multimodality combined. Researchers concluded that navigational bronchoscopies are safe "with the potential for high diagnostic yield, in particular using newer techniques such as [RAB], CBCT, and tomosynthesis-guided [ENB]." However, "studies showed a large amount of heterogeneity, making comparisons difficult."

Tsai et al. (2023) completed a single-center, retrospective study to compare the diagnostic performance of ENB to VNB. A total of 35 patients were included in the study with 19 undergoing ENB and 16 undergoing VNB. Inclusion criteria included "age ≥ 18 years, pulmonary lesions of unknown origin, failure to have the tumor tissue pathologically diagnosed after evaluation in an interdisciplinary setting, and willingness to undergo the novel navigation bronchoscopy by both patients and their families." Exclusion criteria included "inability to tolerate general anesthesia, presence of coagulopathies, long-term use of anticoagulants, abnormal platelet counts and function, history of airway bleeding, and incomplete medical records." Both procedures were completed according to manufacturer's instructions for each navigation system. The ENB procedures were completed without the use of fluoroscopy, radial EBUS, or other procedural techniques (e.g., cytology brushing or bronchoalveolar lavage). Mean distance to the lesion from the pleural space was 16.1±11.7mm (range 1.0-41.0mm). Approximately 32 lesions had a positive air-bronchus sign. Researchers noted that success rate was higher in the VNB group (93.8%) compared to the ENB group (78.9%). No procedure-related complications or mortality occurred. This study showed that VNB "is a clinically feasible alternative to

ENB…[and] the adoption of cone-beam CT may increase the navigation success rate, irrespective of the presence of the [positive] bronchus sign." However, researchers noted that only one operator performed the VNB procedures, increasing the potential for bias due to experience.

A study (NCT05739695) is currently being completed to compare VNB to radial EBUS and a combination of both bronchoscopic techniques. The primary outcomes measured will be the diagnostic efficacy and safety of each method. The study is scheduled to be completed in March 2025 (ClinicalTrials.gov 2024).

A study (NCT05358041) is being completed to compare CBCT-guided ENB to CBCT-guided RAB for peripheral and central lung lesions. The primary outcomes measured will be the difference in diagnostic yield between both approaches and "the sensitivity of ENB with fixed angle catheter versus robotic shape sensing bronchoscopy with articulating catheter." The study had an estimated completion date of November 2022. No data has currently been published (ClinicalTrials.gov 2022).

National/Specialty Organizations

The **American College of Chest Physicians (ACCP)** published *Diagnosis and Management of Lung Cancer: Evidence-Based Clinical Practice Guidelines (3rd ed.).* The guidelines and recommends that in individuals with a solid, indeterminate nodule that measures > 8 mm in diameter, nonsurgical biopsy (which includes VNB) may be performed when diagnostic imaging tests are not in agreement with clinical pretest probability, probability of malignancy is < 60%; a suspected benign diagnosis requires specific medical treatment; or when a fully informed patient desires proof of a malignant diagnosis prior to surgery. When the risk of surgical complications is high, the proof of malignancy holds value. The guidelines further state that in individuals who are at high risk for pneumothorax following transthoracic needle biopsy, bronchoscopic techniques are preferred for nodules located in proximity to a patent bronchus (ACCP 2013).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

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 the primary bronchoscopy procedure)

HCPCS (Healthcare Common Procedure Coding System) Codes

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

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APPROVAL HISTORY

06/12/2024 Policy reviewed, no changes to criteria. Policy title changed from "Virtual Bronchoscopy & Electromagnetic Navigational Bronchoscopy for Evaluation of Peripheral Pulmonary Lesions."

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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