Molina Clinical Policy
Virtual Bronchoscopy & Electromagnetic Navigational Bronchoscopy for Evaluation of Peripheral Pulmonary Lesions: Policy No. 206

Last Approval: 6/14/2023
Next Review Due By: June 2024

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

Electromagnetic Navigation Bronchoscopy (ENB) was developed to increase the range of lung sites accessible by transbronchial needle aspiration (TBNA), particularly the peripheral lung by guiding bronchoscopy instruments to reach lung targets for diagnostic procedures such as transbronchial biopsy, brushing, or TBNA. This technique uses a special catheter with a sensor probe that is inserted through the working channel of a regular flexible bronchoscope. The probe is then steered through the distal airways beyond the third generation of airways, guided by an electromagnetic guidance system. This allows peripheral lung masses or abnormal areas to be sampled even if they cannot be accessed directly by regular bronchoscope. Examples of ENB devices include the superDimension i-Logic System (Covidien) and the inReach which was the first-generation device developed by superDimension Inc., followed by the second-generation device, the i-Logic System (Dhillon & Harris 2017).

Virtual Bronchoscopy Navigation (VBN) consists of three-dimensional computer-generated images of the tracheobronchial tree that allow “fly-through” visualization of airways. Imaging for the software is typically obtained via non-contrast enhanced computed tomography scans and these scans may be completed using manufacturer-specific protocols. These data are then analyzed by software to reconstruct three dimensional and endoluminal views of the airways. Virtual bronchoscopy has the advantage of being noninvasive, being able to define the airways out to the seventh generation and providing valuable information about the condition of the distal airways beyond an obstruction when a flexible bronchoscope cannot pass the obstructing lesion. It also provides valuable information about the location of structures outside of the airways (e.g., lymph nodes or blood vessels). The major limitation of virtual bronchoscopy is its inability to sample lesions. In most cases, virtual bronchoscopy is performed prior to flexible or ultrathin bronchoscopy to plan a sampling procedure (Shepherd 2022). Sampling procedures may include lung biopsies, bronchoalveolar lavages, and/or brushings. Virtual bronchoscopy is not widely available, and its diagnostic characteristics are still being appraised (Islam 2021).

Robotic-Assisted Bronchoscopy (RAB), also commonly referred to as robotic bronchoscopy, is an emerging technology that utilizes a robotic system to navigate the airways using a three-dimensional model reconstructed by device-specific software. Imaging for the software is obtained via chest computed tomography scans that are then loaded into the software system to create the three-dimensional model used for navigation. The system functions similar to robotic-assisted surgery devices in that a control panel and video monitors are used to navigate the patient’s airways using the three-dimensional model that is displayed on one video monitor while the physician is able to visualize the airways via direct camera feedback using another video monitor attached to the system. A catheter is used for navigation and procedures rather than a bronchoscope. The catheter contains a “tool channel” that allows the operator to utilize proprietary biopsy needles for sampling as well as other third-party tools, such as brushes. Fiducial marker placement can also be performed using RAB. The catheter is smaller in diameter than a standard bronchoscope, allowing for navigation of smaller airways not typically able to be achieved with standard bronchoscopy due to the larger diameter of the bronchoscope (Chen et al. 2021; Islam 2021; Shepherd 2022).

Peripheral Pulmonary Lesions occur beyond the segmental bronchi and are not visible by bronchoscopy (Shen et al. 2021).

COVERAGE POLICY

ENB is considered **medically necessary** for members who require a pathological diagnosis of pulmonary lesions when*:

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

*Note: EBUS may be performed in conjunction with ENB to diagnose and stage lung cancer.

VBN and RAB for evaluation of pulmonary lesions **is considered investigational, experimental, and unproven** due to insufficient evidence published in the peer reviewed medical literature. Additional peer-reviewed randomized controlled trials with larger sample sizes and long-term outcomes are required to define their role in the diagnostic pathway for lung cancer and management of peripheral lung lesions.

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

The overall body of evidence is low in the evaluation of the role of VBN and ENB as a diagnostic tool for peripheral lung lesions since most studies evaluated patient cohorts and lacked controls. To evaluate the role of VBN and ENB among existing diagnostic bronchoscopy techniques, additional randomized controlled studies are needed to determine diagnostic accuracy of this test alone or as an adjunct to other tests and assess long-term health outcomes including lung cancer mortality. A summary of the most relevant medical evidence is outlined below.

Virtual Bronchoscopy

There is conflicting evidence regarding overall diagnostic yield between VBN-assisted (VBNA) and non-VBN-assisted (NVBNA) groups. A meta-analysis completed by Jiang et al. (2020) found diagnostic yield to be approximately 1.69 times higher in VBNA 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 PPL size was ≤ 20 mm.

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

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

Electromagnetic Navigation Bronchoscopy

The NAVIGATE study was a prospective, multicenter, cohort study evaluating ENB using the superDimension navigation system (Folch et al. 2019). 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 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 VBN. The meta-analysis included 32 studies (16 each for ENB and VBN) with a total of 1981 patients. The meta-analysis revealed that ENB had an advantage over VBN 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 VBN.

Yutaka et al. (2022) completed a retrospective study to compare the results of ENB transbronchial lung biopsies to VBN transbronchial lung biopsies at a single institution. The study included 100 ENB samples and 50 VBN samples. Overall results showed improved diagnostic yield in ENB as compared to VBN (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 VBN.

Robotic-Assisted Bronchoscopy

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 PPLs. 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 RP-EBUS to exclude the presence of endobronchial disease and to provide topical anesthesia based on the discretion of the bronchoscopist. PPL 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.

The **American College of Chest Physicians (ACCP)** published *Evidence-Based Clinical Practice Guidelines (3rd ed.)* and recommends that in individuals with a solid, indeterminate nodule that measures > 8 mm in diameter, nonsurgical biopsy (which includes VBN) 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	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	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

APPROVAL HISTORY

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.
12/16/2015, 09/15/2016, 9/19/2017, 7/10/2018	Policy reviewed, no changes.
08/25/2014	New policy.

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