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

Last Approval: 6/8/2022
Next Review Due By: June 2023

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. Recent advances in helical (spiral) computed tomography (CT) hardware allow the rapid acquisition of volumetric data of the entire airways in a relatively short time. 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 important information about the condition of the distal airway beyond an obstruction when a flexible bronchoscope cannot pass the obstructing lesion. It also provides important 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 almost all cases, virtual bronchoscopy is performed prior to rigid or flexible bronchoscopy in order to plan a procedure. Virtual bronchoscopy is not widely available, and its diagnostic characteristics are still being appraised (Islam, 2021).

Peripheral Pulmonary Lesions occur beyond the segmental bronchus and not visible by bronchoscopy.

COVERAGE POLICY

Virtual bronchoscopy navigation (VBN) and electromagnetic navigational bronchoscopy (ENB) for evaluation of pulmonary lesions **are 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 its 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

Two prospective, multicenter, randomized, comparative studies have been published that compare virtual bronchoscopic navigation (VBN) combined with ultrathin bronchoscopy (Asano et al., 2013) or endobronchial ultrasound (Ishida et al., 2011). In the first trial, 350 patients with peripheral pulmonary lesions (diameter, <30 mm) were randomly assigned to VBN-assisted or non-VBN assisted groups. There was no significant difference in the diagnostic yield between the VBN-assisted group (67.1%) and the non-VBN-assisted group (59.9%; P = 0.173). In the second study, 199 patients with small peripheral pulmonary lesions (diameter <30 mm) were randomly assigned to VBN-assisted (VBNA) or non-VBN-assisted (NVBNA) groups. The diagnostic yield was not significantly higher for the VBNA than for the NVBNA group (80.4% vs 67.0%; p=0.032). Additional evidence consists of comparative studies and case series. Results of these studies are conflicting but suggest that VB assistance is safe and shortens procedural time of EBUS-guided bronchoscopy for PLL (Wong et al., 2014; Oshige et al., 2011; Shinagawa et al., 2007). Diagnostic rates were 35%, 61.4% and 94.7% for lesions <10, 10-20, and >20 mm, respectively (Tachihara et al., 2007).

Electromagnetic Navigation Bronchoscopy

There is one randomized controlled trial (RCT) that evaluated the efficacy of the superDimension ENB System. This RCT enrolled 120 patients who underwent transbronchial forceps biopsy of peripheral lung lesions guided by the superDimension System alone (ENB group: 20 men, 19 women; mean age 55 years; mean lesion size 28 millimeters [mm]), EBUS alone (EBUS group, 23 men, 16 women; mean age 54 years; mean lesion size 25 mm), or both methods combined (ENB+EBUS group, 25 men, 15 women; mean age 51 years; mean lesion size 24 mm). No fluoroscopic guidance was used. If the biopsy procedure did not give a definitive diagnosis, patients were referred for open surgical biopsy. Two patients, one each from the ENB Group and the EBUS Group, refused open biopsy and were excluded from the study. At baseline, there were no statistically significant differences among the 3 groups in demographics except for lesion size (P<0.05). The final histopathological diagnosis indicated that 26 (22%) lesions were benign and 92 (78%) were malignant. There were no statistically significant differences between the groups in the incidence of benign versus malignant lesions (Eberhardt et al., 2007). Additional evidence consists of prospective and retrospective studies. Results of these studies show that ENB using the superDimension System allows physicians to perform biopsies of peripheral lesions and mediastinal lymph nodes with a diagnostic yield of approximately 43% to 79% for ENB alone, from 84% to 91% for ENB combined with rapid on-site cytopathological examination (ROSE), and from 50% to 88% for ENB combined with EBUS (Chee et al., 2013; Lamprecht et al., 2012; Seijo et al., 2010; Pearlstein et al., 2012; Wilson & Bartlett, 2007).

A retrospective subanalysis of a randomized controlled trial compared VBN combined with EBUS RCT and involved 194 patients with 30-mm or smaller peripheral pulmonary lesions. The difference in the diagnostic yield between the VBN-assisted (VBNA) and non-VBN-assisted (NVBNA) groups was investigated. Within the bronchus sign-positive subgroup, the diagnostic yield in the VBNA and NVBNA groups was 94.4% (68/72) and 77.8% (56/72), respectively, showing a significantly higher yield in the VBNA group (p=0.004; odds ratio: 4.9). The yield was particularly high for lesions smaller than 20 mm (94.6% vs. 70.7%; p=0.006), lesions located in the peripheral third of the lung field (95.1% vs.71.4%; p=0.005) and lesions invisible on P-A radiographs (90.0% vs. 41.7%; p=0.026). The results found that the addition of VBN to R-EBUS improved the diagnostic yield (Asano et al., 2015).

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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 virtual bronchoscopic navigation (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).

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT	Description
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance when performed; with placement of fiducial markers, single or multiple
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 Codes – N/A

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

06/08/2022 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, 09/15/2016,0 9/19/2017, 7/10/2018 Policy reviewed, no changes.
08/25/2014 New policy.

REFERENCES

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from CMS.

National and Specialty Organizations

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2. American College of Radiology (ACR). Diagnostic radiology: Practice parameter for the performance of chest radiography. Published 2017. Available from ACR.
3. Scottish Intercollegiate Guidelines Network (SIGN). Management of lung cancer: Guideline no. 137. Available from SIGN.

Peer Reviewed Publications

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Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. Hayes. Computed Tomography (CT)-guided lung biopsy with the superDimension i-Logic System (Covidien). Available from Hayes. Published April 2013. Updated March 2014. Archived May 2016.
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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*