| Subject: Virtual Bronchoscopy and Electromagnetic Navigational Bronchoscopy for Evaluation of Peripheral Pulmonary Lesions | | Original Effective Date: 8/25/2014 |
|---|---|---|
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*This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.*[1]

## DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

*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. [18]

*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 (eg, 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. [19]

*Peripheral pulmonary lesions* are defined as lesions occurring beyond the segmental bronchus and not visible by bronchoscopy.

## RECOMMENDATION [5-21]

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.

## SUMMARY OF MEDICAL EVIDENCE [5-18]

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 [5] or endobronchial ultrasound. [6] 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). [5] 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). [6] Additional evidence consists of comparative studies and case series. [8-11] Results of these studies are conflicting but suggest that VB assistance is safe and shortens procedural time of EBUS-guided bronchoscopy for PLL. [8-9 11] Diagnostic rates were 35%, 61.4% and 94.7% for lesions <10, 10-20, and >20 mm, respectively. [10]

*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. [7] 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. [12-16]

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. [17]

*Professional Society Guidelines* [2-4]

*American College of Chest Physicians (ACCP):* In the third edition of its Evidence-Based Clinical Practice Guidelines, the ACCP 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. [2]

**CODING INFORMATION** THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

| 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 | Description |
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| | N/A |

| ICD-9 | Description: [For dates of service prior to 10/01/2015] |
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| 162.3 | Malignant neoplasm of upper lobe bronchus or lung |
| 162.4 | Malignant neoplasm of middle lobe bronchus or lung |
| 162.5 | Malignant neoplasm of lower lobe bronchus or lung |
| 162.8 | Malignant neoplasm of other parts of bronchus or lung |
| 162.9 | Malignant neoplasm of bronchus or lung, unspecified |
| 196.1 | Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes |
| 197.0 | Secondary malignant neoplasm of lung |

| ICD-10 | Description: [For dates of service on or after 10/01/2015] |
|---|---|
| C34.00-C34.92 | Malignant neoplasm of main bronchus |
| C77.0-C77.9 | Secondary and unspecified malignant neoplasm of lymph nodes |

## RESOURCE REFERENCES


**Government Agency**

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**Professional Society Guidelines**

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**Other Resources**

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***Review/Revision History***

*8/25/14: Policy created*

*12/16/15, 9/15/16, 9/19/17, 7/10/18: Policy reviewed, no changes.*