Electromagnetic Navigation Bronchoscopy

Description

Electromagnetic navigation bronchoscopy (ENB) is intended to enhance standard bronchoscopy by providing a 3-dimensional roadmap of the lungs and real-time information about the position of the steerable probe during bronchoscopy. The purpose of ENB is to allow navigation to distal regions of the lungs, so that suspicious lesions can be biopsied and to allow fiducial markers placement.

OBJECTIVE

The objective of this evidence review is to determine whether the use of electromagnetic navigation bronchoscopy improves the net health outcome in individuals with either suspicious peripheral pulmonary lesions, enlarged mediastinal lymph nodes (MLN), or lung tumors requiring placement of fiducial markers.
POLICY STATEMENT

When flexible bronchoscopy alone, or with endobronchial ultrasound, are considered inadequate to accomplish the diagnostic or interventional objective, electromagnetic navigation bronchoscopy (ENB) may be considered **medically necessary** to:

- establish a diagnosis of suspicious peripheral pulmonary lesion(s) or
- place fiducial markers within lung tumor(s) prior to treatment

Electromagnetic navigation bronchoscopy is considered **investigational** for use with flexible bronchoscopy for the diagnosis of mediastinal lymph nodes as well as all other uses not covered above.

POLICY GUIDELINES

Bronchoscopists performing ENB requires specific training in the procedure.

Enlarged Mediastinal Nodes was an early indication for ENB which has been largely replaced by EBUS. One could consider it in the uncommon scenario in which linear EBUS is not available and the patient is having an ENB procedure for a peripheral nodule in any case.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In 2004, the superDimension/Bronchus™ inReach™ system (superDimension) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The system includes planning and navigation software, a disposable extended working channel, and a disposable steerable guide. The FDA-cleared indication is for displaying images of the tracheobronchial tree that aids physicians in guiding endoscopic tools in the pulmonary tract. The device is not intended as an endoscopic tool; it does not make a diagnosis; and it is not approved for pediatric use. As of June 2016, the current version of the product is the Medtronic SuperDimension Navigation System (Medtronic) (K173244).

In 2009, the ig4™ EndoBronchial system (Veran Medical) was cleared for marketing by the FDA through the 510(k) process. The system was considered to be substantially equivalent to the inReach™ system and is marketed as the SPiN Thoracic Navigation System™ (K170023).

In April 2018, LungVision (Body Vision Medical) was cleared for marketing by the FDA through the 510(k) process (K172955). The FDA determined that this device was substantially equivalent to existing devices for use "segment previously acquired 3D CT [computed tomography] datasets and overlay and register these 3D segmented data sets with fluoroscopic live X-ray images of the same anatomy in order to support catheter/device navigation during pulmonary procedure". FDA product code: EOQ.

Several other navigation software-only systems have been cleared for marketing by the FDA through the 510(k) process. They include:

- In 2008, the LungPoint virtual bronchoscopic navigation (VPN) system (Broncus Technologies).
- In 2010, the bf-NAVI VPN system (Emergo Group).

FDA product codes: JAK, LLZ.
**RATIONAL**

**Summary of Evidence**

For individuals who have suspicious peripheral pulmonary lesion(s) when flexible bronchoscopy alone or with endobronchial ultrasound is inadequate to sample the pulmonary lesion(s), the evidence includes meta-analyses, an RCT, and uncontrolled observational studies. A 2015 meta-analysis of 17 studies of ENB reported a large pooled positive likelihood ratio but a small negative likelihood ratio (0.22; 95% CI 0.15 to 0.32). Similarly, a 2014 meta-analysis of 15 studies found that navigation success was high, but diagnostic yield (64.9; 95% CI 59.2 to 70.3) and negative predictive value (NPV) (52.1; 95% CI 43.5 to 60.6) were relatively low. Both systematic reviews assessed the methodological quality of the evidence as low. Results from two large prospective multicenter uncontrolled studies, AQuiRE and NAVIGATE, provide information about test characteristics and safety of ENB. An analysis of more than 500 patients included in the AQuiRE (American College of Chest Physicians Quality Improvement Registry, Evaluation, and Education) registry found a diagnostic yield of ENB that was lower than in other studies, and lower than bronchoscopy without ENB or endobronchial ultrasound (EBUS). In the U.S. cohort of the NAVIGATE study, the 12-month diagnostic yield was 72.9%. Overall, 4.3% of patients experienced pneumothorax, and pneumothorax requiring hospitalization or intervention occurred in 35 of 1215 patients (2.9%). Bronchopulmonary hemorrhage overall occurred in 2.5% of patients overall and Common Terminology Criteria for Adverse Events (CTCAE) grade 2 or higher in 1.5%. There were no deaths related to the ENB device. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. ENB is generally reserved for the most difficult patients, who are poor or borderline candidates for surgery and transthoracic sampling. In this context, the "low yield" observed in observational studies was actually high for this highly selected population. ENB, when used as an option in the armamentarium of the bronchoscopist, is a highly useful and low-risk modality for proper diagnosis and staging of lung cancer. For example, patients who are able to achieve a positive biopsy result through ENB benefit by getting a diagnostic result to appropriately guide treatment while avoiding transthoracic needle biopsy which has a 2-4 times higher risk of pneumothorax than a bronchoscopic biopsy approach. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have enlarged MLNs who receive ENB with flexible bronchoscopy, the evidence includes an RCT and observational studies. There is less published literature on ENB for diagnosing MLN than for diagnosing pulmonary lesions. One RCT identified found higher sampling and diagnostic success with ENB-guided transbronchial needle aspiration (TBNA) than with conventional TBNA. EBUS, which has been shown to be superior to conventional TBNA, was not used as the comparator. The RCT did not report the diagnostic accuracy of ENB for identifying malignancy, and this was also not reported in uncontrolled studies. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input is not generally supportive of a clinically meaningful improvement in net health outcome. MLN diagnosis was an early indication for ENB which has been largely replaced by EBUS. One could consider it in the uncommon scenario in which linear EBUS is not available and the patient is already having an ENB procedure for a peripheral nodule. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment when flexible bronchoscopy alone or with endobronchial ultrasound is inadequate to place the markers near the pulmonary lesion(s), the evidence includes one comparative observational study and several case series. The relevant outcomes are health status measures and treatment-related morbidity. In the largest series, a subgroup analysis of 258 patients from the NAVIGATE study, the subjective assessment of outcome was that 99.2% of markers were accurately placed and 94.1% were retained at follow-up (mean 8.1 days post-procedure). Pneumothorax of any grade occurred in 5.4% of patients, and grade 2 or higher pneumothorax occurred in 3.1%. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. The key advantage of ENB placement is the markedly reduced risk of pneumothorax compared to the transthoracic approach. Patients being treated with targeted radiation are typically those with advanced respiratory disease who cannot undergo surgical resection. They are also more at risk for pneumothorax and resultant further complications. As the markers need to be near and not necessarily in a lesion,
the accuracy advantage of a transthoracic approach is outweighed by the safety advantage of ENB over a transthoracic approach. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network (v.4.2018) practice guidelines on non-small-cell lung cancer state that the strategy for diagnosing lung cancer should be individualized and the least invasive biopsy with the highest diagnostic yield is preferred as the initial diagnostic study.\(^2^2\)

- "Patients with central masses and suspected endobronchial involvement should undergo bronchoscopy.
- Patients with peripheral (outer one-third) nodules may benefit from navigational bronchoscopy, radial EBUS [endobronchial ultrasound], or transthoracic needle aspiration...
- Patients with suspected nodal disease should be biopsied by EBUS, EUS [endoscopic ultrasound], navigation biopsy, or mediastinoscopy."

American College of Chest Physicians

The American College of Chest Physicians (2013) updated its guidelines on the diagnosis of lung cancer.\(^2^3\) Regarding electromagnetic navigation bronchoscopy, the guidelines stated: "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 College noted that the procedure can be performed with or without fluoroscopic guidance and has been found to complement radial probe ultrasound. The strength of evidence for this recommendation was grade 1C ("strong recommendation, low- or very-low-quality evidence").

British Thoracic Society

The British Thoracic Society (2011) published guidelines on advanced diagnostic and therapeutic flexible bronchoscopy in adults.\(^2^4\) The guidelines included the following recommendation: "Electromagnetic bronchoscopy may be considered for the biopsy of peripheral lesions or to guide transbronchial needle aspiration for sampling mediastinal lymph nodes." This was a grade D recommendation, meaning that it was based on nonanalytic studies (eg, case series, expert opinion) or data extrapolated from observational studies.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
REFERENCES


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**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 2012</td>
<td>New policy</td>
<td>Policy updated with literature search; Policy statement changed to ENB with flexible bronchoscopy medically necessary for the diagnosis of solitary pulmonary nodules (SPN). References added renumbered or removed.</td>
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<tr>
<td>June 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review. No change to policy statements. References 9, 13, and 17 were added.</td>
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<tr>
<td>March 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review. No change to policy statements. Reference 3 added.</td>
</tr>
<tr>
<td>March 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 13, 2019; references added. Medically necessary statement changed to include ENB when flexible bronchoscopy alone or with endobronchial ultrasound are inadequate, and changed the indicated populations to include: suspicious peripheral pulmonary lesion(s) or lung tumor(s) who need fiducial marker placement prior to treatment. Investigational policy statement added for use with flexible bronchoscopy for the diagnosis of mediastinal lymph nodes as well as all other uses not included above.</td>
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<tr>
<td>September 2019</td>
<td>Replace policy</td>
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