BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.122 Electromagnetic Navigational Bronchoscopy

Annual Effective Policy Date: October 1, 2024

Original Policy Date: June 2012

Related Policies:

2.04.142 - Molecular Testing in the Management of Pulmonary Nodules
6.01.10 - Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

Electromagnetic Navigational Bronchoscopy

Description

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, 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 **investigationa**l 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 electromagnetic navigation bronchoscopy (ENB) require specific training in the procedure.

Enlarged mediastinal nodes were an early indication for ENB which has been largely replaced by endobronchial ultrasound. One could consider it in the uncommon scenario in which linear endobronchial ultrasound is not available and the individual 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).

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™.

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.

Two ENB systems are currently available, the SPiN Thoracic Navigation System (Veran Medical Technologies) and the superDimension™ navigation system (Medtronic).

RATIONALE

Summary of Evidence

For individuals who have suspicious peripheral pulmonary lesion(s) when flexible bronchoscopy alone or with endobronchial ultrasound are inadequate to sample the pulmonary lesion(s), the evidence includes meta-analyses, a randomized controlled trial (RCT), and uncontrolled prospective observational studies. Relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. A 2020 meta-analysis of 40 studies and a 2015 meta-analysis of 17 studies of ENB reported a large pooled positive likelihood ratio but a small negative likelihood ratio (0.2 to 0.22). Similarly, a 2014 meta-analysis of 15 studies found that navigation success was high, but diagnostic yield (64.9; 95% confidence interval [CI], 59.2 to 70.3) and negative predictive value (52.1; 95% CI, 43.5 to 60.6) were relatively low. The systematic reviews assessed the methodological quality of the evidence as low. Results from 2 large prospective multicenter uncontrolled studies, AQuiRE (American College of Chest Physicians Quality Improvement Registry, Evaluation, and Education) and NAVIGATE (Clinical Evaluation of superDimension Navigation System for Electromagnetic Navigation Bronchoscopy), provide information about test characteristics and safety of ENB. An analysis of more than 500 patients included in the AQuiRE registry found a diagnostic yield of ENB that was lower than in other studies, and lower than bronchoscopy without ENB or endobronchial ultrasound. In the US cohort of the NAVIGATE study, the 2-year diagnostic yield was 69.8%. Overall, 4.3% of patients experienced pneumothorax, and grade 2 or higher pneumothorax occurred in 2.9% of patients. Overall, bronchopulmonary hemorrhage occurred in 2.5% of patients, and grade 2 or higher bronchopulmonary hemorrhage in 1.6% of patients. There were no deaths related to the ENB device. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have enlarged mediastinal lymph nodes who receive ENB with flexible bronchoscopy, the evidence includes a RCT and case series.. Relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. There is less published literature on ENB for diagnosing mediastinal lymph nodes than for diagnosing pulmonary lesions. One RCT identified found higher sampling and diagnostic success with ENB-guided transbronchial needle aspiration than with conventional transbronchial needle aspiration. Endobronchial ultrasound, which has been shown to be superior to conventional transbronchial needle aspiration, 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment when flexible bronchoscopy alone or with endobronchial ultrasound are inadequate to place the markers near the pulmonary lesion(s), the evidence includes 1 comparative observational study and several noncomparative observational studies and case series. 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 postprocedure). Pneumothorax of any grade occurred in 5.4% of patients, and grade 2 or higher pneumothorax occurred in 3.1%. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Chest Physicians

In 2013, the American College of Chest Physicians updated its guidelines on the diagnosis of lung cancer.[26,]Regarding ENB, 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").

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network (v.3.2023) 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.[27,]

- "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."

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.

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

Date	Action	Description
June 2012	New policy	
June 2013	Replace policy	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.
March 2014	Replace policy	Policy updated with literature review. No change to policy statements. References 9, 13, and 17 were added.
March 2015	Replace policy	Policy updated with literature review. No change to policy statements. Reference 3 added.
September 2019	Replace policy	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.
September 2020	Replace policy	Policy updated with literature review through May 26, 2020; no references added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through May 5, 2021; reference added. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through April 21, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
September 2023	Replace policy	Policy updated with literature review through May 8, 2023; reference added. Policy statements unchanged.
September 2024	Replace policy	Policy updated with literature review through April 22, 2024; no reference added. Policy statements unchanged.