# Electromagnetic Navigation Bronchoscopy

**Policy #** 00247
Original Effective Date: 01/20/2010
Current Effective Date: 02/08/2021

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Stereotactic Radiosurgery and Stereotactic Body Radiotherapy is addressed separately in medical policy 00045.*

*Note: Molecular Testing in the Management of Pulmonary Nodules is addressed separately in medical policy 00562.*

## When Services Are Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider electromagnetic navigation bronchoscopy (ENB) to establish a diagnosis of suspicious peripheral pulmonary lesion(s) or to place fiducial markers within lung tumor(s) prior to treatment to be **eligible for coverage**** when flexible bronchoscopy alone, or with endobronchial ultrasound, are considered inadequate to accomplish the diagnostic or interventional objective.

## When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers electromagnetic navigation bronchoscopy (ENB) for use with flexible bronchoscopy for the diagnosis of mediastinal lymph nodes as well as all other uses not covered above, to be **investigational.***

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# Policy Guidelines

Bronchoscopists performing electromagnetic navigation bronchoscopy (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.

# Background/Overview

**Pulmonary Nodules**

Pulmonary nodules are identified on plain chest radiographs, or chest computed tomography scans. Although most nodules are benign, some are cancerous, and early diagnosis of lung cancer is desirable because of the poor prognosis when it is diagnosed later.

**Diagnosis**

The method used to diagnose lung cancer depends on a number of factors, including lesion size, shape, location, as well as the clinical history and status of the patient. Peripheral lung lesions and solitary pulmonary nodules (most often defined as asymptomatic nodules <6 mm) are more difficult to evaluate than larger, centrally located lesions. There are several options for diagnosing malignant disease but none of the methods is ideal. Sputum cytology is the least invasive approach. Reported sensitivity rates are relatively low and vary widely across studies; sensitivity is lower for peripheral lesions. Sputum cytology, however, has a high specificity; and a positive test may obviate the need for more invasive testing. Flexible bronchoscopy, a minimally invasive procedure, is an established approach to evaluate pulmonary nodules. The sensitivity of flexible bronchoscopy for diagnosing bronchogenic carcinoma has been estimated at 88% for central lesions and 78% for peripheral lesions. For small peripheral lesions (<1.5 cm in diameter), the sensitivity may be as low as 10%. The diagnostic accuracy of transthoracic needle aspiration for solitary pulmonary nodules tends to be higher than that of bronchoscopy; the sensitivity and specificity are both approximately 94%. A disadvantage of transthoracic needle aspiration is that a pneumothorax develops in 11% to 25% of patients, and 5% to 14% require insertion of a chest tube. Positron emission tomography scans are also highly sensitive for evaluating pulmonary nodules yet may miss lesions less than 1 cm in size. A lung biopsy is the criterion standard for diagnosing pulmonary nodules but is an invasive procedure.

Advances in technology may increase the yield of established diagnostic methods. Computed tomography scanning equipment can be used to guide bronchoscopy and bronchoscopic transbronchial needle biopsy but have the disadvantage of exposing the patient and staff to radiation. Endobronchial ultrasound by radial probes, previously used in the perioperative staging of lung cancer, can also be used to locate and guide sampling of peripheral lesions. Endobronchial ultrasound is reported to increase the diagnostic yield of flexible bronchoscopy to at least 82%, regardless of lesion size or location.

**Marker Placement**
Another proposed enhancement to standard bronchoscopy is electromagnetic navigation bronchoscopy. Electromagnetic navigation bronchoscopy enhances 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 electromagnetic navigation bronchoscopy is to allow navigation to distal regions of the lungs. Once the navigation catheter is in place, any endoscopic tool can be inserted through the channel in the catheter to the target. This includes insertion of transbronchial forceps to biopsy the lesion. Also, the guide catheter can be used to place fiducial markers. Markers are loaded in the proximal end of the catheter with a guidewire inserted through the catheter.

# FDA or Other Governmental Regulatory Approval

**U.S. Food and Drug Administration (FDA)**
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™‡.

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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/Source

## 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.

The following conclusions are based on a review of the evidence, including but not limited to, published evidence and clinical expert opinion, solicited via BCBSA's Clinical Input Process.

## 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, 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% confidence interval 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% confidence interval 59.2 to 70.3) and negative predictive value (52.1; 95% confidence interval 43.5 to 60.6) were relatively low. Both systematic reviews assessed the methodological quality of the evidence as low. Results from 2 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 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 US 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 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 mediastinal lymph nodes who receive ENB with flexible bronchoscopy, the evidence includes a randomized controlled trial and observational studies. 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 randomized controlled trial identified found higher sampling and diagnostic success with ENB-guided transbronchial needle aspiration than with conventional transbronchial needle aspiration. EBUS, which has been shown to be superior to conventional transbronchial needle aspiration, was not used as the comparator. The randomized

controlled trial 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. Mediastinal lymph nodes 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 are inadequate to place the markers near the pulmonary lesion(s), the evidence includes 1 comparative observational study and several 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%. 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

**Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers,

input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise dnoted.

**2019**
In response to requests, while this policy was under review in 2019, clinical input on the use of electromagnetic navigation bronchoscopy was received from 2 specialty society respondents offering a combined society-level response on behalf of both organizations, including input from physicians with academic medical center affiliations.

Evidence from clinical input is integrated within the Rationale section summaries and the Summary of Evidence.

**Practice Guidelines and Position Statements**

**National Comprehensive Cancer Network**
Current National Comprehensive Cancer Network (v.5.2020) 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.

- "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**
In 2013, the American College of Chest Physicians updated its guidelines on the diagnosis of lung cancer. 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**
In 2011, the British Thoracic Society published guidelines on advanced diagnostic and therapeutic flexible bronchoscopy in adults. 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.

**Ongoing and Unpublished Clinical Trials**
Some ongoing trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trial**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| *Ongoing* | | | |
| NCT02410837[a,b] | NAVIGATE: Clinical Evaluation of super Dimension™‡ Navigation System for Electromagnetic Navigation Bronchoscopy™‡ | 2500 | Nov 2019 |
| NCT03628222[a] | Transbronchial Lung Biopsy Guided by Electromagnetic Navigation Bronchoscopy: A Prospective, Randomized, Multicenter, Superiority Study | 226 | Jun 2020 |

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.
[b]Preliminary results have been published in Khandar et al (2017), Bowling et al (2019), and Folch et al (2018)

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# Policy History

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| | |
|---|---|
| 01/07/2010 | Medical Policy Committee approval |
| 01/20/2010 | Medical Policy Implementation Committee approval. New policy. |
| 10/01/2010 | Coding revision only |
| 01/06/2011 | Medical Policy Committee review |
| 01/19/2011 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 02/02/2012 | Medical Policy Committee review |
| 02/15/2012 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 02/07/2013 | Medical Policy Committee review |
| 02/20/2013 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 02/06/2014 | Medical Policy Committee review |
| 02/19/2014 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 04/02/2015 | Medical Policy Committee review |

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|---|---|
| 04/20/2015 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 04/07/2016 | Medical Policy Committee review |
| 04/20/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes |
| 04/06/2017 | Medical Policy Committee review |
| 04/19/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 04/05/2018 | Medical Policy Committee review |
| 04/18/2018 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 04/04/2019 | Medical Policy Committee review |
| 04/24/2019 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 09/05/2019 | Medical Policy Committee review |
| 09/11/2019 | Medical Policy Implementation Committee approval. Coverage for peripheral pulmonary lesions and fiducial marker placement changed from investigational to eligible for coverage and revised to specify subgroups of patients for whom flexible bronchoscopy alone or with endobronchial ultrasound are inadequate. |
| 01/03/2020 | Medical Policy Committee review |
| 01/08/2020 | Medical Policy Implementation Committee approval. Wording added to coverage statement for clarification to read…who need “tissue sampling of the lesion or” fiducial marker placement… |
| 01/07/2021 | Medical Policy Committee review |
| 01/13/2021 | Medical Policy Implementation Committee approval. Replaced our Eligible for coverage statement with BCBSA’s medically necessary statement. |

Next Scheduled Review Date: 01/2022

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# Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type | Code |
|---|---|
| CPT | 31626, 31627 |
| HCPCS | C9751 |
| ICD-10 Diagnosis | All related diagnoses |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.