Electromagnetic Navigation Bronchoscopy

Policy #  00247
Original Effective Date:  01/20/2010
Current Effective Date:  04/24/2019

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.

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 pulmonary lesions and mediastinal lymph nodes to be investigational.*

Based on review of available data, the Company considers electromagnetic navigation bronchoscopy (ENB) for the placement of fiducial markers to be investigational.*

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
Electromagnetic Navigation Bronchoscopy

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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 guide wire 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...
Electromagnetic Navigation Bronchoscopy

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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 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 System²‡.

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In April 2018, LungVision (Body Vision Medical) was cleared for marketing by FDA through the 510(k) process (K172955). 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 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.

Rationale/Source
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.

For individuals who have suspicious peripheral pulmonary lesion(s) who receive ENB with flexible bronchoscopy, the evidence includes meta-analyses, a randomized controlled trial (RCT), and a number of observational studies. Relevant outcomes are test accuracy and validity, other test
performance measures, and treatment-related morbidity. For ENB, a high negative predictive value or small negative likelihood ratio is desirable because it indicates that patients who test negative would not need additional interventions. A recent meta-analysis reported a large pooled positive likelihood ratio but a modest negative likelihood ratio. Similarly, a 2014 meta-analysis found that navigation success was high, but diagnostic yield and negative predictive value were relatively low. Both meta-analyses judged the quality of published studies to be low. The single RCT found higher a diagnostic yield when both ENB and endobronchial ultrasound were used, compared with either intervention alone but did not include a group without ENB or endobronchial ultrasound. Most uncontrolled studies had small sample sizes. In the AQuiRE registry study, which included more than 500 patients receiving ENB in practice, diagnostic accuracy was lower than in other studies. A large multicenter uncontrolled study is underway. Known as NAVIGATE, an interim analysis of the first 1000 patients reported a 4.9% rate of pneumothorax of any grade and 3.2% rate for pneumothorax of grade 2 or higher. Findings for diagnostic accuracy from NAVIGATE are not yet available. Current data are insufficient to identify potential patient selection criteria or to determine the diagnostic accuracy of ENB when used in clinical practice. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have enlarged mediastinal lymph node(s) who receive ENB with flexible bronchoscopy, the evidence includes an RCT and observational studies. Relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. The RCT found higher sampling and diagnostic success with ENB-guided transbronchial needle aspiration than with conventional transbronchial needle aspiration. Endobronchial ultrasound, which has been shown 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. 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 who receive ENB with flexible bronchoscopy, the evidence includes a controlled study and several uncontrolled studies. Relevant outcomes are other test performance measures, health status measures, and treatment-related morbidity. The controlled study compared markers placed transcutaneously under computed tomography or fluoroscopic guidance or transbronchially with ENB. However, data were only available for 8 patients who had markers placed with ENB. Several case series were identified, but comparative data are needed to conclude the safety and efficacy of ENB for fiducial marker placement. In the largest series, an interim analysis of the NAVIGATE
Electromagnetic Navigation Bronchoscopy

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Original Effective Date: 01/20/2010
Current Effective Date: 04/24/2019

study, the subjective assessment of outcome was that 99% were accurately replaced and 94% were retained at follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

**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.

- “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. 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. 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
Electromagnetic Navigation Bronchoscopy

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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 currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

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<th>Trial Name</th>
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<th>Completion Date</th>
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<tr>
<td>NCT02410837</td>
<td>NAVIGATE: Clinical Evaluation of superDimension™‡ Navigation System for Electromagnetic Navigation Bronchoscopy™‡</td>
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<td>NCT01779388</td>
<td>Bronchoscopy Assisted by Electromagnetic Navigation (EMN) in the Diagnosis of Small Pulmonary Nodules</td>
<td>120</td>
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NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

**References**
Electromagnetic Navigation Bronchoscopy

Policy # 00247
Original Effective Date: 01/20/2010
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Electromagnetic Navigation Bronchoscopy

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01/07/2010 Medical Policy Committee approval

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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
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.

Next Scheduled Review Date: 04/2020

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Page 9 of 11
Electromagnetic Navigation Bronchoscopy

Policy # 00247
Original Effective Date: 01/20/2010
Current Effective Date: 04/24/2019

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 2018 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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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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<td>All related diagnoses</td>
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*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
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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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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