

Medical Benefit		Effective Date: 04/01/13	Next Review Date: 01/20
Preauthorization	No	Review Dates: 09/10, 09/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17, 01/18, 01/19	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With suspicious pulmonary lesion(s) 	Interventions of interest are: <ul style="list-style-type: none"> • Electromagnetic navigation bronchoscopy with flexible bronchoscopy 	Comparators of interest are: <ul style="list-style-type: none"> • Flexible bronchoscopy only • Computed tomography–guided needle biopsy • Endobronchial ultrasound with flexible bronchoscopy 	Relevant outcomes include: <ul style="list-style-type: none"> • Test accuracy • Test validity • Other test performance measures • Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> • With enlarged mediastinal lymph node(s) 	Interventions of interest are: <ul style="list-style-type: none"> • Electromagnetic navigation bronchoscopy with flexible bronchoscopy 	Comparators of interest are: <ul style="list-style-type: none"> • Flexible bronchoscopy only • Computed tomography–guided needle biopsy • Endobronchial ultrasound with flexible bronchoscopy 	Relevant outcomes include: <ul style="list-style-type: none"> • Test accuracy • Test validity • Other test performance measures • Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> • With lung tumor(s) who need fiducial marker placement 	Interventions of interest are: <ul style="list-style-type: none"> • Electromagnetic navigation bronchoscopy with flexible bronchoscopy 	Comparators of interest are: <ul style="list-style-type: none"> • Placement of fiducial markers using computed tomography or ultrasound guidance 	Relevant outcomes include: <ul style="list-style-type: none"> • Other test performance measures • Health status measures • Treatment-related

DESCRIPTION

Electromagnetic navigation bronchoscopy (ENB) is intended to enhance standard bronchoscopy by providing a three-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.

POLICY

Electromagnetic navigation bronchoscopy (ENB) is considered **medically necessary** in patients with solitary pulmonary nodules in which:

- malignancy is reasonably suspected and
- it has been determined that a tissue diagnosis is required and
- percutaneous lung biopsy is considered high risk and low probability for diagnostic yield and
- standard bronchoscopy and/or endobronchial ultrasound (EBUS) are considered low probability for diagnostic yield.

ENB is considered **medically necessary** in patients with an identified lung lesion(s) and a coexisting cancer in whom:

- further determination of the lung lesion may impact the staging of the primary malignancy, and the treatment and
- percutaneous lung biopsy is considered high risk and low probability for diagnostic yield and
- standard bronchoscopy and/or EBUS are considered low probability for diagnostic yield.

Electromagnetic navigation bronchoscopy is considered **medically necessary** for the placement of fiducial markers in patients who are to undergo radiotherapeutic treatment of malignant solitary pulmonary nodules when:

- they are not surgical candidates and radiation treatment is the preferred treatment and
- it is determined that the location of the nodules makes placement of fiducial markers by a transthoracic approach likely to be associated with high risk of developing significant pneumothorax.

Electromagnetic navigation bronchoscopy is considered **medically necessary** for the placement of fiducial markers to help localize a nodule by fluoroscopy during thorascopic excision that would otherwise not be palpable without a thoracotomy.

All other uses of ENB are considered **investigational**.

BACKGROUND

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 smaller than six 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 (smaller than 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 inser-

tion of a chest tube. Positron emission tomography scans are also highly sensitive for evaluating pulmonary nodules yet may miss lesions less than one cm in size. A lung biopsy is the criterion standard for diagnosing pulmonary nodules but is an invasive procedure.¹⁻³

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.¹

Marker Placement

Another proposed enhancement to standard bronchoscopy is electromagnetic navigation bronchoscopy. Electromagnetic navigation bronchoscopy enhances standard bronchoscopy by providing a three-dimensional road-map 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.

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 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.

RELATED PROTOCOLS

Endobronchial Ultrasound for Diagnosis and Staging of Lung Cancer

Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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