



MASSACHUSETTS

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Medical Policy Electromagnetic Navigation Bronchoscopy

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Policy Number: 203

BCBSA Reference Number: 7.01.122

NCD/LCD: NA

Related Policies

- Stereotactic Radiosurgery & Fractionated Stereotactic Radiosurgery, #[277](#)
- Endobronchial Ultrasound for Diagnosis and Staging of Lung Cancer, #[715](#)
- Molecular Testing in the Management of Pulmonary Nodules, #[029](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Electromagnetic navigation bronchoscopy is considered [INVESTIGATIONAL](#) for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes

Electromagnetic navigation bronchoscopy is considered [INVESTIGATIONAL](#) for the placement of fiducial markers.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO Blue SM	This is not a covered service.
Medicare PPO Blue SM	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance when performed; with computer-assisted, image-guided navigation

Description

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.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 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.

Summary

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 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.

Policy History

Date	Action
11/2018	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
7/2017	New references added from BCBSA National medical policy.
7/2016	New references added from BCBSA National medical policy.
11/2015	Added coding language.
3/2015	New references added from BCBSA National medical policy.
4/2014	New references added from BCBSA National medical policy.
2/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group – Cardiology and Pulmonology. No changes to policy statements.
8/1/2010	Medical Policy #203 effective 8/1/2010 created.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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