MASSACHUSETTS

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Medical Policy

Electromagnetic Navigation Bronchoscopy

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Policy Number: 203

BCBSA Reference Number: 7.01.122 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

- Cerebrospinal Fluid and Urinary Biomarkers of Alzheimer Disease, #581
- Endobronchial Ultrasound for Diagnosis and Staging of Lung Cancer, #715
- Stereotactic Radiosurgery & Fractionated Stereotactic Radiosurgery, #277

Policy

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

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 **INVESTIGATIONAL** for use with flexible bronchoscopy for the diagnosis of mediastinal lymph nodes as well as all other uses not covered above.

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)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.

Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

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 above medical necessity criteria MUST be met for the following codes to be covered 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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
J98.4	Other disorders of lung
R91.1	Solitary pulmonary nodule
R91.8	Other nonspecific abnormal finding of lung field

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

Lung cancer is the leading cause of cancer-related death in the U.S., with an estimated 236,740 new cases and 130,180 deaths due to the disease in 2022.[1,] The stage at which lung cancer is diagnosed has the greatest impact on prognosis. Localized disease confined to the primary site has a 60% relative 5-year survival but accounts for only 22% of lung cancer cases at diagnosis.[1,2,] Mortality increases sharply with advancing stage and metastatic lung cancer has a relative 5-year survival of 6%.[1,] In addition to tumor stage, other factors such as age, sex, race/ethnicity, and performance status are independent prognostic factors for survival in patients with lung cancer. The average age at diagnosis is about 70 years and most people diagnosed with lung cancer are 65 years of age or older. The lifetime risk of lung cancer is approximately 1 in 15 for men and 1 in 17 for women, with an increased risk in people who smoke. Rates of lung cancer have been dropping among men over the past few decades, but only for about the last decade in women. Black men are about 12% more likely to develop lung cancer compared to White men, although Black men are less likely to develop small cell lung cancer when compared to White men. Among women, the rate of lung cancer is about 16% lower for Black versus White women.

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 are 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.[3,4,5,]

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.[3,]

Marker Placement

Another proposed enhancement to standard bronchoscopy is electromagnetic navigation bronchoscopy (ENB). 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 ENB 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.

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.

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.

Policy History

Date	Action
8/2022	Annual policy review. Description, summary and references updated. Policy statements unchanged.

9/2020	Annual policy review. Medically necessary policy statement edited for clarity to separate out indications; statements otherwise unchanged.
12/2019	Annual policy review. Populations for indications 1 (peripheral pulmonary lesions) and 3 (fiducial marker placement) revised to specify subgroups of patients for whom flexible bronchoscopy alone or with endobronchial ultrasound are inadequate. Policy statements changed to medically necessary. Clarified coding information. Effective 12/1/2019.
11/2018	Annual policy review. Description, summary and references updated. Policy statements unchanged.
7/2017	Annual policy review. New references added.
7/2016	Annual policy review. New references added.
11/2015	Added coding language.
3/2015	Annual policy review. New references added.
4/2014	Annual policy review. New references added.
2/2013	Annual policy review. New references added.
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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