MASSACHUSETTS

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Medical Policy

Endobronchial Ultrasound for Diagnosis and Staging of Lung Cancer

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Policy Number: 715

BCBSA Reference Number: 6.01.58
NCD/LCD: N/A

Related Policies

Electromagnetic Navigation Bronchoscopy, #203

Policy

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

Endobronchial ultrasound guidance with transbronchial needle biopsy may be considered **MEDICALLY NECESSARY** for the evaluation of peripheral pulmonary lesions in patients with suspected lung cancer when all of the following criteria are met:

- Tissue biopsy of the peripheral pulmonary lesion is required for diagnosis
- The peripheral pulmonary lesion is not accessible using standard bronchoscopic techniques.

Endobronchial ultrasound guidance with transbronchial needle biopsy is considered **MEDICALLY NECESSARY** for mediastinal staging in patients with diagnosed lung cancer when all of the following criteria are met:

- The patient is suitable and willing to undergo specific treatment for lung cancer, with either curative or palliative intent
- Tissue biopsy of abnormal mediastinal lymph nodes seen on imaging is required for staging and specific treatment planning
- Abnormal lymph nodes seen on imaging are accessible by EBUS-TBNA biopsy.

Endobronchial ultrasound is considered **NOT MEDICALLY NECESSARY** for diagnosis and staging of lung cancer when the above criteria are not met.

Endobronchial ultrasound is considered **INVESTIGATIONAL** for all other indications.

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
31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures
31653	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures
31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transendoscopic endobronchial ultrasound (ebus) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s) (list separately in addition to code for primary procedure[s])

Description

LUNG CANCER

Individuals who are suspected of having lung cancer may present with widely differing signs and symptoms related to the type of cancer (eg, non-small-cell lung cancer [NSCLC] vs small-cell lung cancer), its location within the lung, and the stage of disease (ie, localized, locoregionally advanced, metastatic). All three of the major parameters of type, location, and stage will dictate subsequent management of the cancer, determining whether it is primarily surgical or requires systemic chemotherapy. Early diagnosis of lung cancer is essential because of the uniformly poor prognosis when cancer is diagnosed later in the disease course.

Approximately 75% to 80% of newly diagnosed lung cancers are NSCLC. The clinical presentation and findings on computed tomography (CT) or a fluorine 18 fluorodeoxyglucose positron emission tomography (PET) scan of the chest will typically permit a presumptive diagnosis of lung cancer and differentiation between NSCLC and small-cell lung cancer. If small-cell lung cancer is suspected based on radiographic characteristics and other clinical findings, a diagnosis is made by whatever means is the least invasive (eg, sputum cytology, thoracentesis if an accessible pleural effusion is present, fine-needle aspiration of a supraclavicular node).[1] The diagnostic technique to evaluate suspected NSCLC is usually dictated by the apparent stage of the disease. NSCLC can present with extensive infiltration of the mediastinum, defined as a mass with no visible lymph nodes, or it may present as a solitary pulmonary nodule that may be bronchogenic or peripheral. In any patient with suspected NSCLC, the diagnosis should be established by the method that has the most favorable risk-benefit ratio.[1]

Diagnosis of Peripheral Pulmonary Nodules

Solitary pulmonary lesions are typically identified on plain chest radiographs or chest CT scans, often incidentally. Although most of these nodules will be benign, some will be cancerous. Peripheral lung lesions and solitary pulmonary nodules (most often defined as asymptomatic nodules <8 mm) are more difficult to evaluate than larger, centrally located lesions. There are several options for diagnosis; however, none of the methods is ideal for safely and accurately diagnosing malignant disease in all patients.[2] Sputum cytology is the least invasive approach.[1] Reported sensitivity rates are relatively low and vary widely across studies, and sensitivity is even 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 the most common approach to evaluating pulmonary nodules. The sensitivity of flexible bronchoscopy for diagnosing bronchogenic carcinoma has been estimated at 88% for central lesions and 78% for peripheral lesions.[2] For small peripheral lesions less than 1.5 cm in diameter, the sensitivity may be as low as 10%, due to the inability to reach into smaller bronchioles.

Transthoracic (percutaneous) needle aspiration, using CT guidance, can be performed for peripheral nodules that are beyond the reach of traditional bronchoscopy. The diagnostic accuracy of transthoracic needle aspiration tends to be as high or higher than that of flexible bronchoscopy for peripheral lesions; the sensitivity and specificity are both greater than 90%.[2] A disadvantage of transthoracic needle aspiration is that a pneumothorax could occur in as many as 15% of patients (range, 1%-15%). Between 1% and 7% will require chest tube insertion. PET scans are also highly sensitive for evaluating pulmonary nodules, yet may miss small lesions less than 1 cm in size. Surgical lung biopsy is the criterion standard for diagnosing pulmonary nodules but is an invasive procedure not indicated for all patients.

Staging of Lung Cancer and Assessment of Mediastinal Involvement

The stage of a lung cancer (its extent through the body) at diagnosis will directly impact the management approach for each patient.[3,4] The first step in staging is to identify whether the patient has the distant metastatic disease (M stage) or if the tumor is confined to the chest; this will determine whether treatment should be aimed at palliation or at a potential cure, respectively. If the primary tumor is confined (T stage), determining whether the mediastinal lymph nodes (N stage) are involved is a crucial factor in guiding therapy.

As with diagnostic procedures, there are a number of options for mediastinal staging. The choice of a noninvasive or invasive staging method is dictated by the patient's condition and whether he or she can tolerate or will elect surgery. Thus, staging procedures may be based on noninvasive imaging methods (ie, CT or PET, or combined PET-CT), or may be fully invasive, such as mediastinoscopy—a surgical procedure that is performed under general anesthesia and is regarded as the reference standard for staging lung cancer.[3]

Recent advances in technology have led to enhancements that may increase the yield of established needle-based diagnostic methods that represent a third approach, between noninvasive and surgical procedures.[1] CT scanning equipment can be used to guide flexible bronchoscopy and bronchoscopic transbronchial needle biopsy but has the disadvantage of exposing the patient and staff to radiation.

Endobronchial Ultrasound with Transthoracic Needle Aspiration
Among its potential applications, endobronchial ultrasound (EBUS) using ultrasound probes can locate and guide the sampling of pulmonary lesions and mediastinal lymphadenopathy.
EBUS uses 2 distinct types of transducers that have specific uses: radial probe and convex probe.
A radial probe EBUS comprises a 20- or 30-MHz rotating transducer to provide high-resolution 360° radial images. The probe is inserted into the airways via a standard therapeutic bronchoscope. With the use of an ultrathin bronchoscope combined with radial probe EBUS through a guide sheath, an endoscopist can reach and visualize the sixth- to eighth-generation bronchi, whereas a traditional bronchoscope can only reach the fourth-generation bronchi. The use of radial probe EBUS imaging allows the physician to verify visually that a lesion has been reached and to maintain position in the periphery to allow a needle biopsy to be performed for diagnosis.[5] These probes do not allow real-time imaging during the biopsy. For biopsy or tissue sampling, the target area is located by radial probe EBUS; the radial probe is subsequently retracted and is replaced with a biopsy or sampling device.

Convex probe EBUS transducers are adjustable within a frequency range of 5 to 12 MHz. Such transducers are incorporated into the structure of a dedicated bronchoscope and provide real-time pie-slice sector views of 50° to 60° parallel to the axis of the bronchoscope. Convex probe EBUS with transbronchial needle aspiration (EBUS-TBNA) also can be used for staging the mediastinal nodes.[6] The curved linear probe technology allows real-time visualization and needle aspiration of a lesion. Because EBUS-TBNA of the mediastinal nodes may be performed under conscious sedation, it may be used in patients who are not surgical candidates but for whom accurate staging is needed to guide choice among systemic treatments, particularly targeted systemic agents such as tyrosine kinase inhibitors.[7]

Summary
Endobronchial ultrasound (EBUS) is an imaging technique for adjunctive use with standard flexible bronchoscopy. It provides an ultrasound-generated image of the lungs beyond the airway walls, extending to peribronchial structures and distal peripheral lung lesions. The purpose of EBUS is to facilitate navigation to distal regions of the lungs and biopsy of peripheral pulmonary nodules; especially suspected cancerous lesions. Another intended use of EBUS is to localize and facilitate biopsy of the mediastinal lymph nodes as part of staging for non-small-cell lung cancer. Both techniques primarily use transbronchial needle aspiration (TBNA) of lesions to obtain tissue samples.

For individuals who have peripheral pulmonary lesions and suspected lung cancer who receive EBUS-guided TBNA (EBUS-TBNA) for diagnosis, the evidence includes recent systematic reviews, meta-analyses, and 2 small randomized trials. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and morbid events. Evidence supports a conclusion that EBUS-TBNA has diagnostic performance characteristics for solitary pulmonary lesions similar to those of traditional flexible bronchoscopy with transthoracic needle aspiration. The evidence also indicates that the safety profile of EBUS-TBNA may be better than the profile of other techniques, as reflected by pneumothorax and chest tube insertion rates. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have lung cancer and mediastinal lymph nodes seen on imaging who receive EBUS-TBNA for staging, the evidence includes systematic reviews and meta-analyses. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and morbid events. Evidence from systematic reviews supports a conclusion that EBUS-TBNA exhibits test performance characteristics similar to other needle-based methods used to stage the mediastinum in patients diagnosed with lung cancer. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Policy History
Date	Action
10/2018	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
10/2017	New references added from BCBSA National medical policy.

3/2016	New references added from BCBSA National medical policy.
1/2016	Clarified coding information.
11/2015	Policy statements clarified that all of the criteria in the policy need to be met. 11/2015.
4/2015	New medical policy describing medically necessary, not medically necessary and investigational indications. Effective 4/1/2015.

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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