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 BlueSM and Medicare PPO BlueSM 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
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO Blue™</td>
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<td>Medicare PPO Blue™</td>
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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

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>31652</td>
<td>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</td>
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<tr>
<td>31653</td>
<td>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</td>
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<tr>
<td>31654</td>
<td>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])</td>
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Description
Individuals who are suspected of having lung cancer may present with widely differing signs and symptoms that are related to the type of cancer (eg, NSCLC vs small-cell lung cancer [SCLS]), its location within the lung, and the stage of disease (ie, localized, locoregionally advanced, metastatic). All 3 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 CT or fluoro18-2-deoxyglucose (FDG) PET scan of the chest typically permit a presumptive
diagnosis of lung cancer and differentiation between NSCLC and SCLC. If SCLC is suspected based on radiographic characteristics and other clinical findings, a diagnosis is made by whatever means is easiest (sputum cytology, thoracentesis if an accessible pleural effusion is present, fine-needle aspiration [FNA] of a supraclavicular node, etc.). However, the diagnosis of suspected NSCLC is usually dictated by the 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.

**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 <6 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. Sputum cytology is the least invasive approach. 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. 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 TNA tends to be as high or higher than that of flexible bronchoscopy for peripheral lesions; the sensitivity and specificity are both greater than 90%. A disadvantage of TNA is that a pneumothorax may occur in as many as 15% of patients, although this number can range from 1% to 15%. About 1% to 7% will require insertion of a chest tube. 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 that is not indicated for all patients.

**Staging of Lung Cancer: 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. The first step in staging is to identify whether the patient has distant metastatic disease (M stage) or the tumor is confined to the chest; this will determine if treatment should be aimed at palliation or at 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 for 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, whether or not he or she can tolerate or will elect surgery. Thus, staging procedures may be based on noninvasive imaging (ie, CT or PET, or combined PET-CT) methods, or 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.

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. 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

Endobronchial ultrasound (EBUS) using ultrasound probes, previously used in the perioperative staging of lung cancer, can also be used to locate and guide sampling of peripheral lesions. With the use of an ultrathin bronchoscope combined with a radial ultrasound probe (R-EBUS) through a guide sheath, a practitioner can reach and visualize the sixth- to eighth-generation bronchi, whereas a traditional bronchoscope can only reach the fourth-generation bronchi. The use of R-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 Curved probe linear array EBUS with 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 with 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.

EBUS uses 2 distinct types of transducers that have specific uses:

1. R-EBUS, and
2. convex-probe curved linear array transducer EBUS.

A radial EBUS probe comprises a 20 or 30 MHz rotating transducer to provide high-resolution 360 radial images. It is inserted into the airways via a standard therapeutic bronchoscope. Radial probes are used to assess the airway wall layers for tumor invasion, tracheal stenosis, or tracheomalacia. These probes do not allow real-time imaging during biopsy. For biopsy or tissue sampling, the target area is located by REBUS; the radial probe is subsequently retracted and is replaced with a biopsy or sampling device.

A convex-probe curved linear array EBUS transducer is 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. Linear EBUSTransbronchial needle aspiration (EBUS-TBNA) is used to diagnose lung lesions and to stage the mediastinal and hilar node stations. In contrast to radial EBUS, the EBUS-TBNA bronchoscope allows for real-time imaging during biopsy because the needle is optically visualized.

Summary

Endobronchial ultrasound (EBUS) is a technique that enhances standard flexible bronchoscopy by providing 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 allow navigation to distal regions of the lungs and facilitate biopsy of suspected cancerous lesions, especially for peripheral pulmonary nodules. Another intended use of EBUS is to examine and biopsy the mediastinal lymph node regions as part of staging for non-small-cell lung cancer (NSCLC). Both techniques use transbronchial needle aspiration (TBNA) of lesions to obtain tissue samples.

Evidence summarized in this Policy shows EBUS-guided TBNA (EBUS-TBNA) exhibits test performance characteristics similar to those of other established methods used to diagnose lung cancer or stage the mediastinum in patients diagnosed with lung cancer. Results from 5 independent meta-analyses showed pooled sensitivities that ranged from 0.88 to 0.93 and pooled specificities of 0.99 to 1.00, very similar to the American College of Chest Physicians (ACCP) findings. Evidence from 2 small randomized controlled trials (RCTs) supports the conclusion that EBUS-guided TBNA has diagnostic performance similar to traditional bronchoscopy for solitary peripheral pulmonary lesions and that EBUS-transthoracic needle aspiration (TNA) has similar accuracy to computed tomography (CT)–guided needle biopsy with lower complications.

The major advantage of EBUS-TBNA over traditional flexible bronchoscopy is that EBUS-TBNA has the ability to penetrate much lower into the bronchial tree. As an alternative to mediastinoscopy for staging, EBUS-TBNA can be performed on an outpatient basis under limited sedation if necessary. EBUS-guided
TBNA methods also may have an enhanced safety profile compared with other non-EBUS needle-based methods and do not expose the patient or providers to radiation from either CT or fluoroscopy.

When a biopsy is indicated to diagnose or stage lung cancer, the choice of technique depends on a number of factors, including the size and location of the lesion(s) needing biopsy. For patients who have peripheral pulmonary nodules that are not accessible by standard bronchoscopy, EBUS-TBNA is a less risky alternative and results in a positive diagnosis in a high proportion of cases. Similarly, for mediastinal biopsy, if the lesions are accessible by EBUS-TBNA, this is the least invasive alternative for making a tissue diagnosis. As a result, EBUS-TBNA may be considered medically necessary for diagnosis or staging of lung cancer when criteria are met.

### Policy History

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<tr>
<th>Date</th>
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<tr>
<td>1/2016</td>
<td>Clarified coding information.</td>
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<tr>
<td>11/2015</td>
<td>Policy statements clarified that all of the criteria in the policy need to be met. 11/2015.</td>
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### 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

### References