



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Endobronchial Ultrasound for Diagnosis and Staging of Lung Cancer

Policy #: 576

Latest Review Date: September 2022

Category: Surgical

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **endobronchial ultrasound guidance with transbronchial needle biopsy** as a **covered benefit** for the **evaluation of peripheral pulmonary lesions in individuals with suspected lung cancer** when **BOTH** of the following criteria are met:

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

Blue Advantage will treat **endobronchial ultrasound guidance with transbronchial needle biopsy** as a **covered benefit** for **mediastinal staging in individuals with diagnosed lung cancer** when **ALL** of the following criteria are met:

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

Blue Advantage will treat **endobronchial ultrasound** as a **non-covered benefit for diagnosis and staging of lung cancer** when the above criteria are not met.

Blue Advantage will treat **endobronchial ultrasound for all other indications** as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

Lung Cancer

Individuals who are suspected of having lung cancer may present with widely differing signs and symptoms that are related to the type of cancer (e.g., NSCLC vs small-cell lung cancer [SCLS]), its location within the lung, and the stage of disease (i.e., localized, locoregionally advanced, metastatic). All three of the major parameters of type, location, and the stage will dictate subsequent management of 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 (FDG) positron emission tomography (PET) scan of the chest will 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 the least invasive (e.g., sputum cytology, thoracentesis if an accessible pleural effusion is present, fine-needle aspiration of a supraclavicular node). 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.

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 are 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 (TNA), 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 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 (i.e., CT or PET, or combined PET-CT) methods, or be fully invasive such as a 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

Among its potential applications, endobronchial ultrasound (EBUS) using ultrasound probes, can be used to locate and guide sampling of pulmonary lesions and mediastinal lymphadenopathy.

EBUS uses two 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 a position in the periphery to allow a needle biopsy to be performed for diagnosis. These probes do not allow real-time imaging during 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. 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.

KEY POINTS:

The most recent literature review was updated through August 2, 2022.

Summary of Evidence

For individuals who have peripheral pulmonary lesions and suspected lung cancer who receive EBUS-TBNA for diagnosis, the evidence includes recent systematic reviews, meta-analyses, and two small randomized trials. The 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 an improvement in the net health outcome.

For individuals who have lung cancer and mediastinal lymph nodes that are seen on imaging who receive EBUS-TBNA for staging, the evidence includes systematic reviews and meta-analyses. The relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and morbid events. Evidence from systematic reviews of observational studies 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 an improvement in the net health outcome.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on non-small-cell lung cancer (v.3.2022) state:

“The least invasive biopsy with the highest yield is preferred as the first diagnostic study.... Patients with peripheral (outer one-third) nodules may benefit from navigational bronchoscopy, radial EBUS [endobronchial ultrasound], or transthoracic needle aspiration (TTNA)... Patients with suspected nodal disease should be biopsied by EBUS, EUS [endoscopic ultrasound], navigational bronchoscopy or mediastinoscopy.”

American College of Chest Physicians

The American College of Chest Physicians (ACCP) has offered a number of evidence-based guidelines on the use of EBUS-guided needle aspiration of pulmonary lesions for diagnosis of lung cancer¹ and mediastinal staging of patients diagnosed with lung cancer (Table 1). A

separate guideline and expert panel report (2016) has addressed the technical aspects of EBUS-guided transbronchial needle aspiration and its use outside the setting of lung cancer.

Table 1. Guidelines on Use of Endobronchial Ultrasound to Diagnose and Stage Lung Cancer

Recommendation	Grade
Diagnosis of peripheral pulmonary nodules	
<p>“2.3.2. In patients suspected of having lung cancer, who have extensive infiltration of the mediastinum based on radiographic studies and no evidence of extrathoracic metastatic disease (negative PET scan), it is recommended that the diagnosis of lung cancer be established by the least invasive and safest method (bronchoscopy with TBNA, endobronchial ultrasound-guided needle aspiration [EBUS-NA], endoscopic ultrasound-guided needle aspiration [EUS-NA], transthoracic needle aspiration [TTNA], or mediastinoscopy).”</p>	1C
<p>“3.3.2.1. In patients suspected of having lung cancer, who have a peripheral lung nodule, and a tissue diagnosis is required due to uncertainty of diagnosis or poor surgical candidacy, radial EBUS is recommended as an adjunct imaging modality.”</p>	1C
Staging of the mediastinum in patients diagnosed with lung cancer	
<p>“4.4.4.3. In patients with high suspicion of N2,3 involvement, either by discrete mediastinal lymph node enlargement or PET uptake (and no distant metastases), a needle technique (endobronchial ultrasound [EBUS]-needle aspiration [NA], EUS-NA or combined EBUS/EUS-NA) is recommended over surgical staging as a best first test.... Remark: In cases where the clinical suspicion of mediastinal node involvement remains high after a negative result using a needle technique, surgical staging (e.g., mediastinoscopy, video-assisted thoracic Surgery [VATS], etc.) should be performed.”</p>	1B

PET: positron emission tomography.

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force recommendations for endobronchial ultrasound have been identified.

KEY WORDS:

Endobronchial Ultrasound, EBUS, Transbronchial needle biopsy, TBNA, lung cancer, Olympus Medical Systems EU-M60 EUS Exera, EVIS EXERA Bronchofibervideoscope, ATL HDI 5000

Ultrasound System, Olympus BF type UC160F-OL8 bronchoscope, ALOKA SSD-Alpha 5/10
 Ultrasound System, Olympus Medical Systems XBF-UC180F-DT8 Ultrasonic
 Bronchofibervideoscope, PENTAX Ultrasound Video bronchoscope EB-1970UK + HI VISION
 Preirus endoscopic ultrasound, Medi-Globe SonoTip® II EBUS-TBNA Needle System, Cook
 EchoTip®, Medi-Globe SonoTip® Pro and Pro Flex EBUS-TBNA

APPROVED BY GOVERNING BODIES:

A number of instruments are commercially available to perform EBUS-TBNA for diagnosis and staging of lung cancer. All have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process and are shown in Table 2.

Table 2. FDA-Cleared Instruments Used to Perform EBUS-TBNA

Device Name	Manufacture	Date Cleared	510(k)	Indications
EVIS EXERA Bronchofibervideoscope, Olympus BF type UC160F- OL8 bronchoscope and its diagnostic ultrasound transducer	Olympus Medical Systems	Aug 2004	K042140	To provide real-time endoscopic US imaging and US-guided FNA, including the upper airways and tracheobronchial tree
EU-M60 EUS EXERA Endoscopic Ultrasound Center	Olympus Medical Systems	Dec 2004	K04327	To acquire and to display high-resolution and high- penetration, real-time endoscopic US B-mode 2D and 3D images, including the upper airways and tracheobronchial tree
XBF-UC180F-DT8 Ultrasonic Bronchofibervideoscope and the ALOKA SSD-Alpha 5/10 Ultrasound System	Olympus Medical Systems	Jul 2007	K070983	To provide real-time endoscopic US imaging and US-guided FNA including the upper airways and tracheobronchial tree
SonoTip® II EBUS-TBNA Needle System	Medi-Globe	May 2009	K091257	For US-guided FNA of submucosal and extraluminal lesions of the tracheobronchial tree

EchoTip® Ultra High Definition Endobronchial Ultrasound Needle	Cook Medical	Jan 2010	K093195	For use in conjunction with an EBUS endoscope to gain access to and sample submucosal and extramural lesions within or adjacent to the tracheobronchial tree through the accessory channel of an EBUS for FNA
PENTAX Ultrasound Video Bronchoscope EB-1970UK + HI VISION Preirus endoscopic ultrasound	PENTAX Medical	Apr 2014	K131946	To provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the pulmonary tract including but not restricted to the nasal passages, pharynx, larynx, trachea, bronchial tree (including access beyond the stem), and underlying areas
SonoTip® Pro and Pro Flex EBUS-TBNA Needle System	Medi-Globe	May 2014	K133763	Intended for US-guided FNA of submucosal and extraluminal lesions of the tracheobronchial tree and gastrointestinal tract (e.g., lymph nodes, abnormal tissue in the mediastinum)
Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle	Boston Scientific	Nov 2015	K151315	For use with EBUS endoscopes for US-guided FNA of the submucosal and extramural lesions of the tracheobronchial tree

EBUS: endobronchial ultrasound; EUS: endoscopic ultrasound; FDA: Food and Drug Administration; FNA: fine-needle aspiration; TBNA: transbronchial needle aspiration; US: ultrasound.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g. aspiration[s]/biopsy[ies], one or two mediastinal and/or hilar lymph node stations or structures. (Effective 01/01/2016)
31653	with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g. aspiration[s]/biopsy[ies], 3 or more mediastinal and/or hilar lymph node stations or structures. (Effective 01/01/2016)
31654	with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s) (Effective 01/01/2016)

PREVIOUS CODING:

31620	Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s]) (Deleted effective 01/01/2016)
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POLICY HISTORY:

Adopted for Blue Advantage, January 2015

Available for comment January 9 through February 22, 2015

Medical Policy Group, December 2015

Medical Policy Group, February 2015

Medical Policy Group, February 2016

Medical Policy Group, October 2017

Medical Policy Group, October 2018 (3): Updates to Key Points, Practice Guidelines, and References. No change in policy statement or intent.

Medical Policy Group, September 2019

Medical Policy Group, September 2020

Medical Policy Group, September 2021

Medical Policy Group, September 2022

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.