



October 4, 2022

ATTN: Evan London, MS, MPH
Director, Medical Policy
Office of Medical Policy and Technology Assessment (OMPTA)
Elevance Health
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Dear Mr. London,

On behalf of our membership, the American Association of Bronchology & Interventional Pulmonology (AABIP), the American Thoracic Society (ATS), and the American College of Chest Physicians (CHEST) appreciate the opportunity to submit our shared comments on the Anthem/Elevance medical policy MED.00099. Our societies represent over 40,000 pulmonary, interventional pulmonary, critical care, and sleep specialists dedicated to the prevention, treatment, research, and cure of respiratory disease, critical care illness, and lung cancer.

We read with great concern your policy that “Navigational Bronchoscopy is considered **investigational and not medically necessary** for all applications.” Our societies include physicians providing care for patients with peripheral lung lesions (PLLs) who are working to improve the provision of lung cancer care in a timely and cost-effective manner. The established published evidence and recognized clinical practice guidelines support **our request and recommendation to archive policy MED.00099 and remove the ‘investigational and not medically necessary’ status for Navigational Bronchoscopy.** Herein we present the evidence based that supports our position.

The current policy points out that most PLLs are diagnosed using transthoracic needle aspiration (TTNA) because it has a higher diagnostic yield than standard bronchoscopy or electromagnetic navigation bronchoscopy (ENB) and is safe in most patients with PLLs. In fact, meta-analyses of TTNA and biopsy published in radiology literature show complication rates that are several times higher than those seen with ENB (Eur Radiol. 2017 Jan;27(1):138-148; J Thorac Oncol. 2022 Apr;17(4):519-531). There are numerous target lesion factors that may reduce diagnostic yield of TTNA and/or contraindications for TTNA: the presence of emphysema or blebs, location near major vessels, uncontrollable cough, a location requiring a significant amount of lung to be traversed or near the diaphragm. In these cases, TTNA may be both inappropriate and higher risk for many patients. Recent cost-effectiveness studies of diagnosis and staging for lung cancer show that CT-guided biopsy alone, when compared with the most cost-effective bronchoscopic strategy, results in more complications, requires more time to complete the evaluation, has a higher rate of undetected mediastinal lymph node involvement (N2-3 disease), and an increased risk of mortality (Chest.



2021; 160(6):2304-2323). Furthermore, deviation from guidelines and performance of a CT-guided biopsy first results in a 17% higher rate of pneumothorax and increased cost by \$ 1,000 per patient. Several meta-analyses have evaluated the risk of pleural recurrence after a TTNA as compared with alternatives (surgery and bronchoscopic biopsy). A recent study (Thorax. 2021 Jun;76(6):582-590) analyzed 2394 patients (TTNA, 1158 patients versus other [bronchoscopy, surgery], 1236 patients) with a median follow-up after surgery of 60.7 months. Compared with other diagnostic procedures, TTNA was associated with a higher risk for ipsilateral pleural recurrence, which manifested solely and concomitantly with other metastases. Furthermore, reductions of time to recurrence, lung cancer-specific survival and overall survival were observed in patients <55 years who underwent TTNA.

Recent published data also suggests that even patients with small, peripheral lesions suspected of lung cancer (T1 tumors) benefit from staging due to the high rate of mediastinal disease (Chest. 2020;158(5):2192-2199). Therefore, committing these patients to a CT-guided biopsy first not only puts them at higher risk for complications, but it will lead to repeat interventions such as subsequent bronchoscopy for staging, and thus, delay the time to treatment and risk tumor upstaging.

Non-coverage of navigational bronchoscopy leaves our patients without an option for minimally invasive sampling to achieve a tissue diagnosis and staging, as indicated. Regarding navigational bronchoscopy and the coverage of procedures for evaluation of pulmonary nodules, over 95% of health plans have chosen to extend coverage to navigational bronchoscopy, either by archiving and inactivating a non-coverage policy or by issuing a positive coverage policy.

- They agree that the evidence for sensitivity and complications rates of navigational bronchoscopy are adequately described in the literature so that use of navigational bronchoscopy is now evidence-based and that navigational bronchoscopy is a component of the Standard of Care in evaluating patients with PLLs.
- They recognize that the trade-offs of specific risks and rewards in the evaluation of individual patients is best done in the context of informed consent between clinicians and patients, based on current guidelines and published evidence.

The clinical guidelines and recommendations published by American College of Chest Physicians (CHEST), American Thoracic Society (ATS), National Comprehensive Cancer Network (NCCN), UpToDate, and Blue Cross Blue Shield Association (BCBSA) confirm the widely accepted evidence-based guideline that navigational bronchoscopy is a standard of care procedure for patients with peripheral lung lesions.

NCCN Non-Small Cell Lung Cancer (NSCLC) 2022 guidelines:

“The preferred biopsy technique depends on the disease site and is described in the NSCLC algorithm. For example, radial endobronchial ultrasound (EBUS),



navigational bronchoscopy, or transthoracic needle aspiration (TTNA) are recommended for patients with suspected peripheral nodules.”

This is now a globally accepted procedure. In fact, British Thoracic Society guidelines for investigation and management of pulmonary nodules recommend augmenting the yield from bronchoscopy using either radial endobronchial ultrasound, fluoroscopy or electromagnetic navigation (ENB) (Thorax. 2015;70:ii1–ii54)

We trust that the information we have outlined, along with support from our colleagues and other professional societies, show that Navigation Bronchoscopy has the evidence base to support its coverage in appropriately selected patients and that it is a Standard of Care approach in evaluating patients with PLLs.

The AABIP, ATS and CHEST appreciate the opportunity to share our views in writing. We would welcome a conference call with appropriate staff at Anthem to discuss our recommendations in more detail. Please contact Ms. Brittany Holcombe (brittany.aabip@gmail.com) or Mr. Gary Ewart (gewart@thoracic.org) or Ms. Suzanne Sletto (ssletto@chestnet.org) to set up a conference call with our clinical experts.

Sincerely,

Ali Musani, MD

Chair, AABIP Advocacy Committee

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Co-Chair, Joint American Thoracic Society/CHEST Clinical Practice Committee

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References:

1. CHEST guidelines
2. ATS guidelines
3. NCCN guidelines
4. Up to Date
5. BCBSA
6. Eur Radiol. 2017 Jan;27(1):138-148;
7. J Thorac Oncol. 2022 Apr;17(4):519-531.



8. Chest. 2021; 160(6):2304-2323
9. Thorax. 2021 Jun;76(6):582-590
10. CHEST. 158(5):2192-2199 (2020)
11. BTS Guidelines (Thorax 2015;70:ii1–ii54)